UCLA Technology Development Group RIA Monthly Training Seminar Series

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HDOC Approval in Clinical Research (review), Auditing and Monitoring of Study Data, and Sponsor Rights to Study Results and Intellectual Property

UCLA Technology Development Group

HDOC Approval Review

UCLA Health | David Geffen School of Medicine

- April 2026 HDOC presentation available on TDG website:
  - https://tdg.ucla.edu/ucla-researchers/research-and-industry-alliances/resources
- Key Points:
  - UCLA Health Data is “any information pertaining to the health, care and treatment of UCLA health patients or health plan members which: (i) Results in a report used in treatment or monitoring of a patient; or (ii) Generates a claim or bill for services that are provided; or (iii) Is used for operations, financial management, population health activities or quality metrics
  - If Sharing UCLA Health Data with third parties or other UC campuses, need HDOC approval or exemption
  - Sharing of UCLA Health Data requires attachment of all mandatory UCLA Health Data Terms, unless specific exemptions are granted by HDOC Committee
  - Please start process early and involve both HDOC and TDG

Use of Health Data for Research

- UCLA Health requires that any third party use of its Health Data results in a tangible outcome that directly or indirectly benefits UCLA Health's own patients and society, in general.

Third Party Health Data Agreements

- Terms that must be included in any contract with a third party involving the use by that third party of Health Data acquired and maintained by UCLA Health. A third party is defined as any for-profit or not-for-profit entity

Key Term

- **Health Data must be de-identified and not include Protected Health Information**: Only de-identified Health Data (de-identified under the HIPAA standards per UCLA Health policy) may be shared. Exceptions to this mandate must be reviewed by the University of California Office of the President (UCOP), per the Interim Guidelines.

Definition of a Clinical Trial

- The NIH defines a clinical trial as a research study in which human subjects are prospectively assigned to one or more interventions (including placebos or controls) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

Not Clinical Trials

- Observational Studies
- Non-Clinical Laboratory Studies
- Human-Subject studies without Intervention
- Epidemiological Studies
- Basic Experimental Studies Involving Humans that do not meet Clinical Trial criteria

Monitoring

- Sponsors of clinical investigations involving human drugs, biological products, medical devices and combination products are required to provide oversight, including ensuring proper monitoring of the investigation.

- Oversight helps to ensure adequate protection of the rights, safety and welfare of participants in the clinical investigation and integrity of the data submitted to the FDA.

Monitoring Definition

ICH GCP E6(R2) definition:

““The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).”

- FDA Guidance: “Monitoring is a QC tool for determining whether study activities are being carried out as planned, so that deficiencies can be identified and corrected.”

Purposes of Clinical Research Monitoring

- **The monitoring activities are conducted to verify:**
  - The rights and well-being of human subjects are protected
  - The reported trial data are accurate, complete, and verifiable from source documents
  - The conduct of the trial complies with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirements

Source Data Verification

- Process check that the data recorded into the CRFs match the source data from source documents
- Source documents include the electronic health record

Source Documents

- Signed consent documents (all versions)
- Clinic notes (outpatient/inpatient)
- Laboratory and pathology reports (local and central)
- Imaging studies, EKG/Echo reports, pulmonary function tests, quality of life questionnaires
- Medication diaries
- Correspondence between study team and subject
- Assessments done to confirm subject's eligibility to enroll in study
- Memos/Notes to File

Source Documents, cont.

- Admission/discharge notes (SAEs)
- Sponsor correspondences related to study subjects (such as protocol waivers and safety reporting)
- Records of subject visits performed at outside facilities
- Documentation of adverse events, and abnormal lab review by the PI or delegated team member
- IP dosing/administration records
- Documents recording research sample collection
- CRFs containing initially recorded study data

Impactful Monitoring Findings

- Subject consented using invalid/expired ICF version
- Study activities conducted prior to obtaining consent
- Subject not followed per applicable version of the protocol
- Missing or inconsistent data into CRFs
- Missed or out of window study assessments
- Missed or delayed reporting of SAEs and deviations
- Transcription errors

Impactful Monitoring Findings, cont.

- Enrollment of an ineligible subject
- HIPAA Breach
- Research blood collected over the set limit
- Non-study team member doing study activity

References

References

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals in Human Use (ICH). 2016. *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*. https://ichgcp.net/. Accessed April 4, 2023.
- U.S. Food and Drug Administration (FDA). 2013. Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring. Guidance for Industry. https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/oversight-clinical-investigations-risk-basedapproach-monitoring. Accessed April 4, 2023.
- U.S. Food and Drug Administration (FDA). 2021. Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergence. Originally published March 2020. https://www.fda.gov/media/136238/download. Accessed April 8, 2021.

Principles Regarding Rights to Future Research Results In University Agreements with External Parties

University of California, Office of the President, 8/26/99, updated RO and Policy Contact Info 5/26/22

1. Open Dissemination of Research Results and Information

Agreements with external parties shall not abridge the ability of University researchers to disseminate their research methods and results in a timely manner. The most fundamental tenet of the University is the freedom to interpret and publish or otherwise disseminate research results in order to support the transfer of knowledge to others and maintain an open academic environment that fosters intellectual creativity.

2. Commitment to Students

Agreements for research relationships with external parties shall respect the University's primary commitment to the education of its students.

3. Accessibility for Research Purposes

Agreements with external parties shall ensure the ability of University researchers to utilize the results of their research to perform future research.

4. Public Benefit

Agreements with external parties shall support the ability of the University to make available for the public benefit in a diligent and timely manner any resulting innovations and works of authorship.

5. Informed Participation.

All individuals involved in research governed by a University agreement with an external party shall have the right and responsibility to understand the rights and obligations related to future research results embodied within the agreement.

6. Legal Integrity and Consistency.

Commitments concerning future research results made in agreements with external parties shall be consistent with all applicable laws and regulations and the University's contractual obligations to others.

7. Fair Consideration for University Research Results.

Agreements with external parties shall provide fair consideration to the University and the general public for granting commercial access to future University research results.

8. Objective Decision-Making

When establishing or conducting University relationships with external parties, decisions made about rights to future research results shall be based upon legitimate institutional academic and business considerations and not upon matters related to the personal financial gain of any individual.

https://policy.ucop.edu/doc/2500487/PrinciplesRegardingResearchResults

University of California Research Data Policy

University of California, Office of the President, 8/9/22

"Ownership of Research Data by the Regents of the University of California is a longstanding precept…The intent of this Policy is to clarify the ownership of and responsibility for Research Data generated during the course of University Research…."

Applies to all Research Data generated or collected during the course of University Research.

Research Data defined as "[r]ecorded information embodying facts resulting from a scientific inquiry, regardless of the form or media in which they may be recorded."

Exclusions:

-patient source documents

-medical records created in the course of clinical care.

- University policies and guidance ensure that such ownership will prevent impediments to the use of Research Data for:
  - Other University Research
  - Sharing with collaborators and academic communities
  - Independent publication of outcomes
  - Creation of Scholarly & Aesthetic Works.
- At each campus, the Vice Chancellor for Research or their designee(s), in consultation with the appropriate campus stakeholders, including the Academic Senate, is responsible for the interpretation, implementation, and oversight of this Policy

https://policy.ucop.edu/doc/2500700/ResearchData

Policy on Inventions, Patents, and Innovation Transfer

University of California, Office of the President, Effective Date 7/1/24

- Applies to:
  - all University employees, non-employees using University Research Facilities, and non-employees using gifts, grants, or contracts received by or through the University.

- Intellectual Property:
  - includes all Inventions, discoveries, developments, systems, methods, and materials, as well as all software and other copyrightable works for which the University retains copyright ownership under the Copyright Ownership Policy or Ownership of Course Materials Policy….also includes any legally recognized rights in the items enumerated in the preceding paragraph, including patents, registered or unregistered copyrights, registered or unregistered trademarks and service marks, and plant variety protection certificates. It also includes the physical embodiments of intellectual effort, for example, models, organisms, machines, devices, designs, apparatus, instrumentation, circuits, biological materials, chemicals, other compositions of matter, and plants.

- University IP:
  - all Intellectual Property wholly or partially created: 1) within the course and scope of University employment, 2) using University Research Facilities, or 3) using gifts, grants, or contracts received by or through the University.

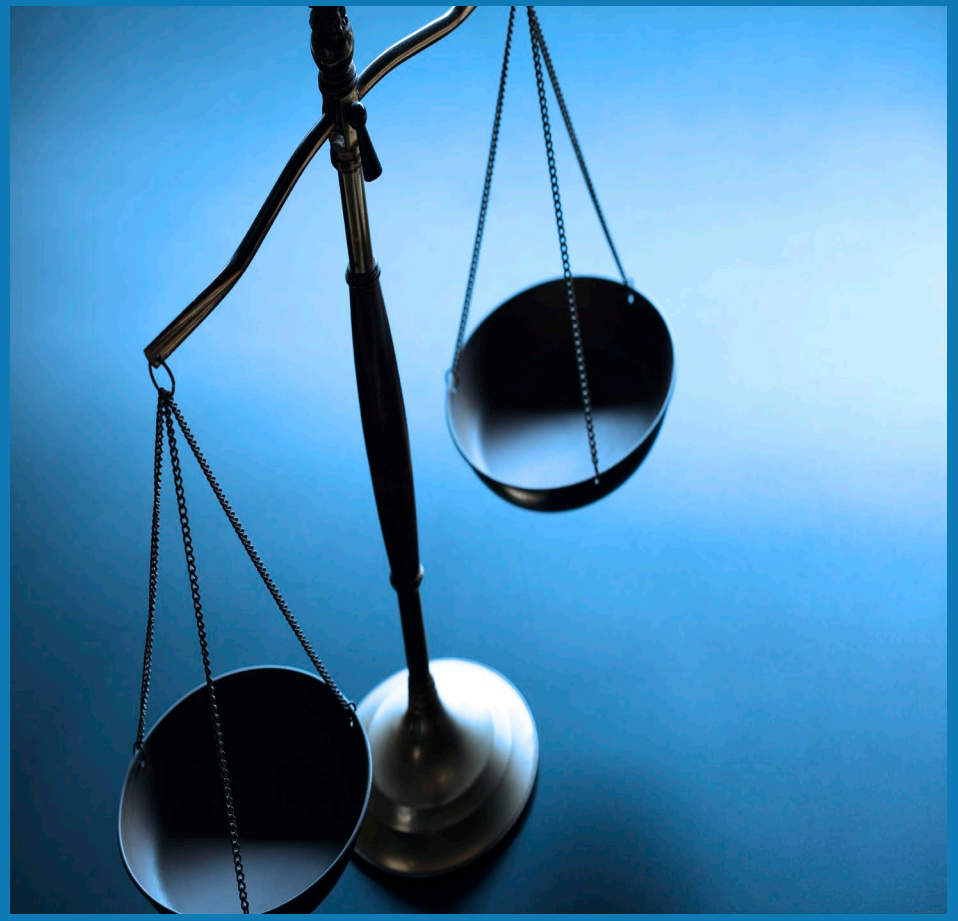
- The University owns University IP.

https://policy.ucop.edu/doc/2500493/PatentPolicy

Balancing Sponsor Interest with UC Policies and Academic Interests in TDG Contracts

- Sponsors may request ownership of:
  - Data
  - Results
  - All IP arising out of the performance of the Study
  - Ownership of all improvements to a product or material
  - Co-ownership of IP solely based on Sponsor's provision of a material, product, or device.

- Other problematic requests:
  - Publication approval mandates beyond review and request to remove confidential information
    - Excessive publication delays
    - Classifying results/data as their confidential information
  - No grant back to UCLA or excessively narrow grant for use of exclusively licensed/sponsor owned data
  - Consideration not reasonable/commensurate with the scope of support and context of proposed research



Standard TDG Sponsored IP/Data Contracting Positions

- Can request our template SRAs and MTAs from your TDG officer
- Data/results owned by UCLA with non-exclusive, royalty free internal research license to company with future ability to negotiate a license to use data/results for commercial purposes
    - Possible to negotiate a commercial license to the data/results along with the SRA either as standalone agreement or within the SRA itself with attachment of standard licensing terms (available on TDG website here: https://tdg.ucla.edu/industry-investors/ready-sign-agreements)
- Ownership of developments or discoveries first conceived and actually reduced to practice in the performance of the Research under this Agreement (**"Inventions"**) will be determined in accordance with United States Patent Law.
- For SRAs, Sponsor receives time-limited, exclusive, first right to negotiate an option or license to University's interests in any Invention
- Sponsor has to disclose intent to exercise the right within 60 days of Invention Disclosure and has 120 days to negotiate/and execute the option or license
- TDG Leadership, Business Development Officers and other appropriate stakeholders involved in review and approval of deviations from the above

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Questions?