



Health

**David Geffen
School of Medicine**

UCLA

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STRATEGIC IRB SUBMISSION: ACCELERATING APPROVAL WITHOUT COMPROMISING COMPLIANCE

DANIELLA ESCOBEDO, MS, PMP, CCRP

PRINCIPAL TRAINER FOR CLINICAL RESEARCH

OFFICE OF CLINICAL RESEARCH

UCLA CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

OBJECTIVES

By the
end of
this
session,
you will:

Understand why pre-submission preparation determines IRB approval efficiency

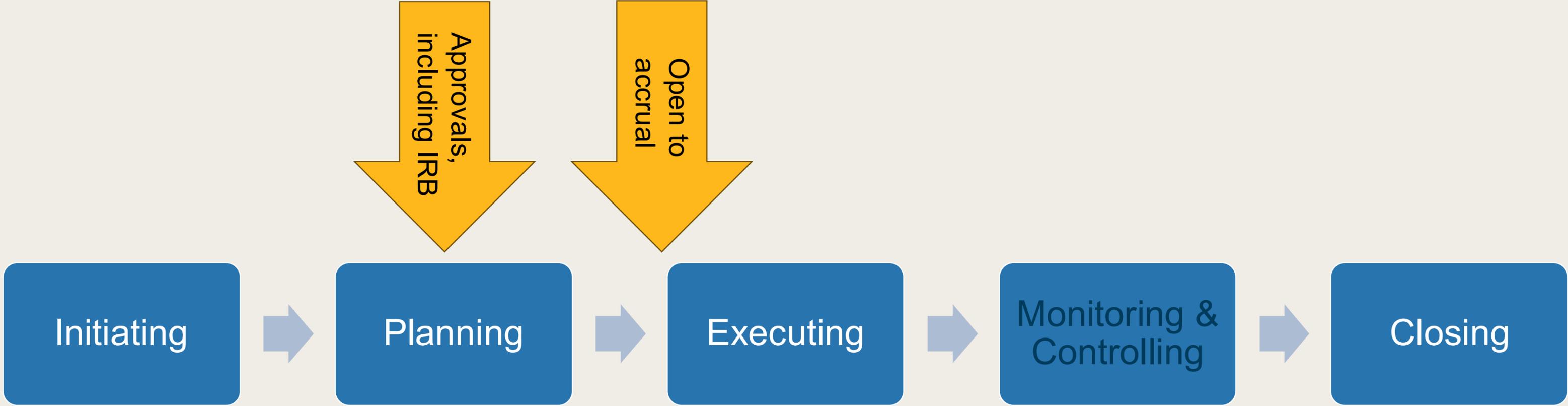
Recognize that IRB approval alone does not authorize study initiation

Identify the parallel approvals required before research can begin

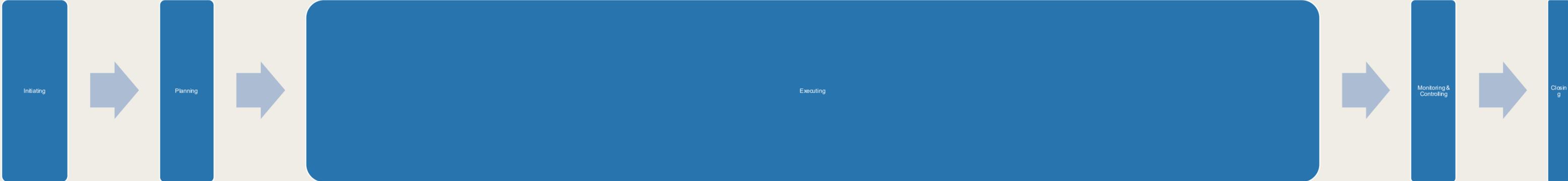
Anticipate common barriers that delay research

Leave with clear pathways for institutional training and support

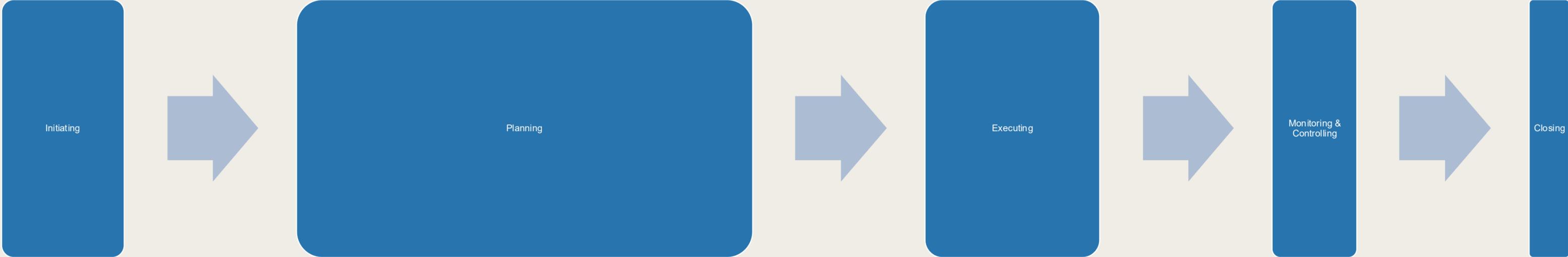
PROJECT PHASES



PROJECT PHASES: PERCEPTION



PROJECT PHASES: REALISTIC



INSTITUTIONAL REQUIREMENTS

UCLA Policy 900

Investigator Directory Search

Principal Investigators that do not meet the criteria for eligibility per policy, must request a PI exception.

Faculty Sponsor

UCLA Policy 991

All activities that constitute “human research” that are performed by UCLA employees/students must be reviewed and approved by the UCLA IRB or be certified exempt from IRB review **prior** to initiation

This includes advertising, recruitment, and/or screening of potential subjects for research, and/or accessing or obtaining identifiable, private information from or about living individuals for the purpose of conducting research, e.g., review of medical records.



UCLA OHRPP

BruinIRB

CareConnect

BruinIRB

Regulatory Document Retention: Florence eBinder

Clinical Research Management System: OnCore

Data Management: REDCap, U-LEAD

ESSENTIAL DEFINITIONS

Any research that involves either the participation of human subjects or the use of human biological specimens, medical charts, or databases with identifying information about humans is considered to be human subject research and requires review.

Guidance Documents

[Determining Which Activities Require UCLA OHRPP/IRB Review](#)

[Determining When Collection or Use of Data and Specimens for Research Requires IRB Review](#)

[Research Conducted by UCLA Students](#)

**DOCUMENTATION OF IRB
EXEMPTION IS A REQUIREMENT**

Will the study require services or resources owned, rented, operated or provided by the UCLA Health System, including but not limited to the following: scheduling, order entry and/or billing of any patient visits and/or clinical services via CareConnect, including but not limited to services provided by any clinical departments within the UCLA Health System and the Clinical and Translational Research Center (CTRC)?

IRB REVIEW TIMELINES

REFERENCE

See “Allow Sufficient Time” section
<https://ohrpp.research.ucla.edu/getting-started/>

FULL COMMITTEE REVIEW

Allow **6-8 weeks** for Full Committee approvals of initial submissions and modifications.

Allow **4 weeks** for Full Committee approval of continuing review submissions.

Each of the 5 IRBs meet twice monthly: [IRB meeting dates and application deadlines](#).

EXPEDITED REVIEW

Allow **2-3 weeks** for Expedited approvals.

EXEMPT REVIEW

Allow **1 week** for Exempt certifications.

EXPEDITED AND EXEMPT RENEWALS/MODIFICATIONS

Allow **1 week** for renewals and modifications to expedited and exempt studies.

Exempt and expedited applications are reviewed in the order received and do not have application deadlines



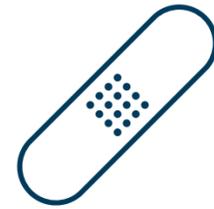
Protocol



Informed Consent
Form*



Investigator's
Brochure*



Device Manual*

- [Guidance: Materials Required for IRB Review and Approval](#)
- [Choose the Right Protocol Template](#)
- [Choose the Right Informed Consent Form Template](#)
- [Template Biomedical IRB Protocol](#)



ADDITIONAL CONSIDERATIONS

ANCILLARY REVIEWS

**MULTICENTER REQUIREMENTS FOR SINGLE IRB VIA IRB
RELIANCE**

CITI TRAINING- WHICH MODULES ARE REQUIRED?

PROJECT MANAGEMENT BEST PRACTICES

AND MANY MORE!

A comprehensive, virtual training program for Principal Investigators, offering advanced tools and strategies to design, manage, and execute clinical research projects with precision, compliance, and leadership excellence

Contact

Daniella Escobedo: descobedo@mednet.ucla.edu

THANK YOU