

Ancillary Studies Evaluation Subcommittee (ASES)

D2d Kick-Off Meeting
July 10, 2013

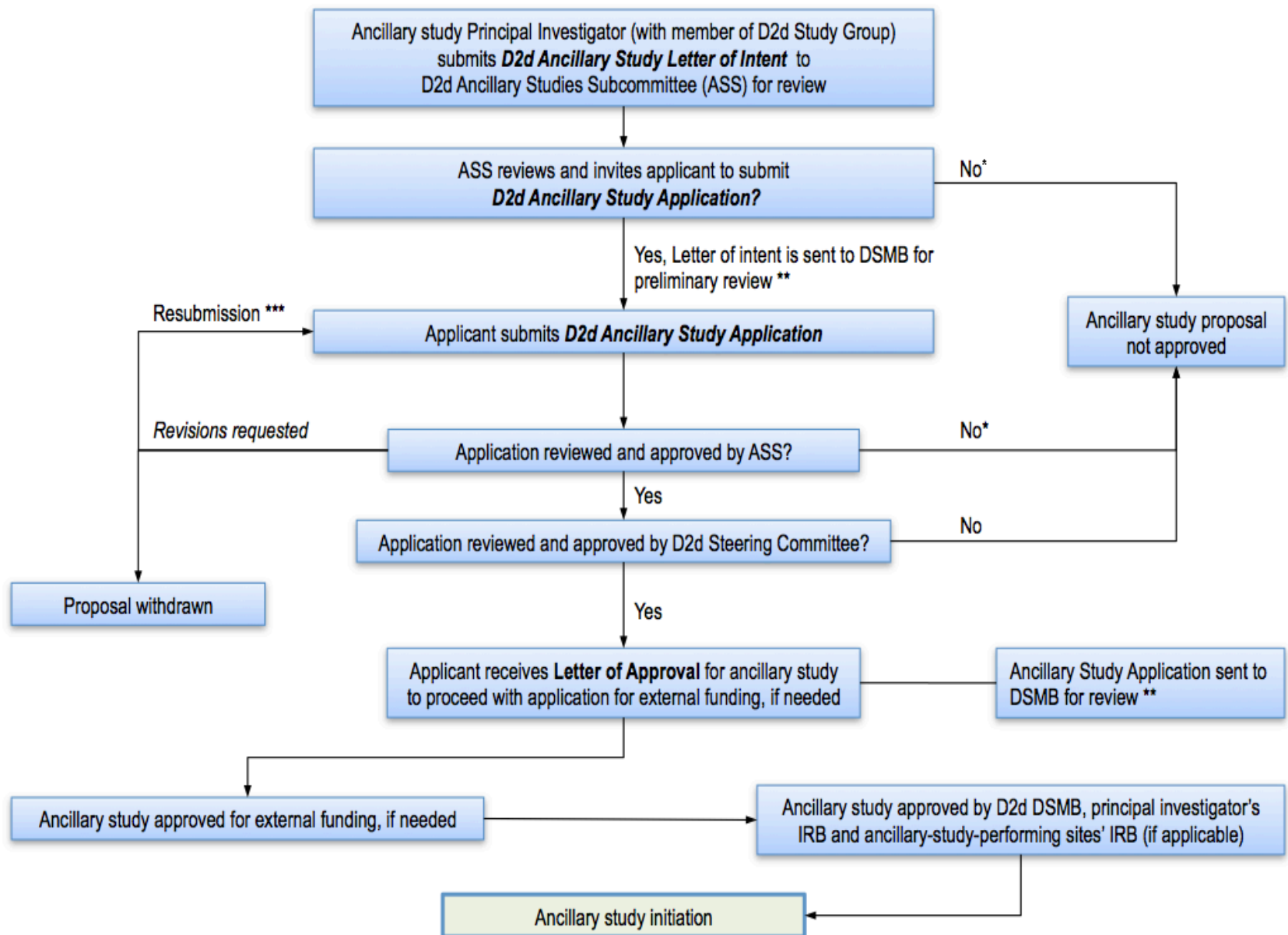
- Other outcomes (e.g. effect of vitamin D supplementation on cardiovascular risk factors [cholesterol profile, C-reactive protein, urine albumin excretion]), as part of distinct ancillary studies requesting additional funds, may be developed in parallel.
- Additional blood (serum and plasma) and urine samples will be collected at the baseline, 6-month and annual visits for banking and available to ancillary studies.
- After D2d is completed, long-term storage of blood and urine samples will be transitioned to the NIDDK Central Repositories.
- At baseline, the study will collect whole blood for future DNA extraction

Ancillary Studies Evaluation Subcommittee (ASES)

- Develops, approves and oversees the ancillary studies policies and procedures
- Solicits ancillary study applications
- Evaluates ancillary study letter of intents and applications and makes recommendations to the Steering Committee regarding the proposals
- Monitors progress of approved ancillary studies
- Seeks guidance from other committees, as needed

ASES Members

- Bess Dawson-Hughes, Chair
- Cyrus Desouza, Vice Chair
- Chhavi Chadha
- Anne Peters
- Taso Pittas
- Richard Pratley
- Philip Raskin
- David Robbins
- Cliff Rosen
- Myrlene Staten
- Jim Ware



* Ancillary study PI may appeal decision to the D2d Steering Committee.

** Approval by D2d DSMB (meets twice yearly) is required prior to study initiation; DSMB approval is not required for investigator to proceed with application for external funding.

*** The ASS will accept only a single major resubmission to the original application.