

D2d Ancillary Studies Evaluation Subcommittee (ASES)

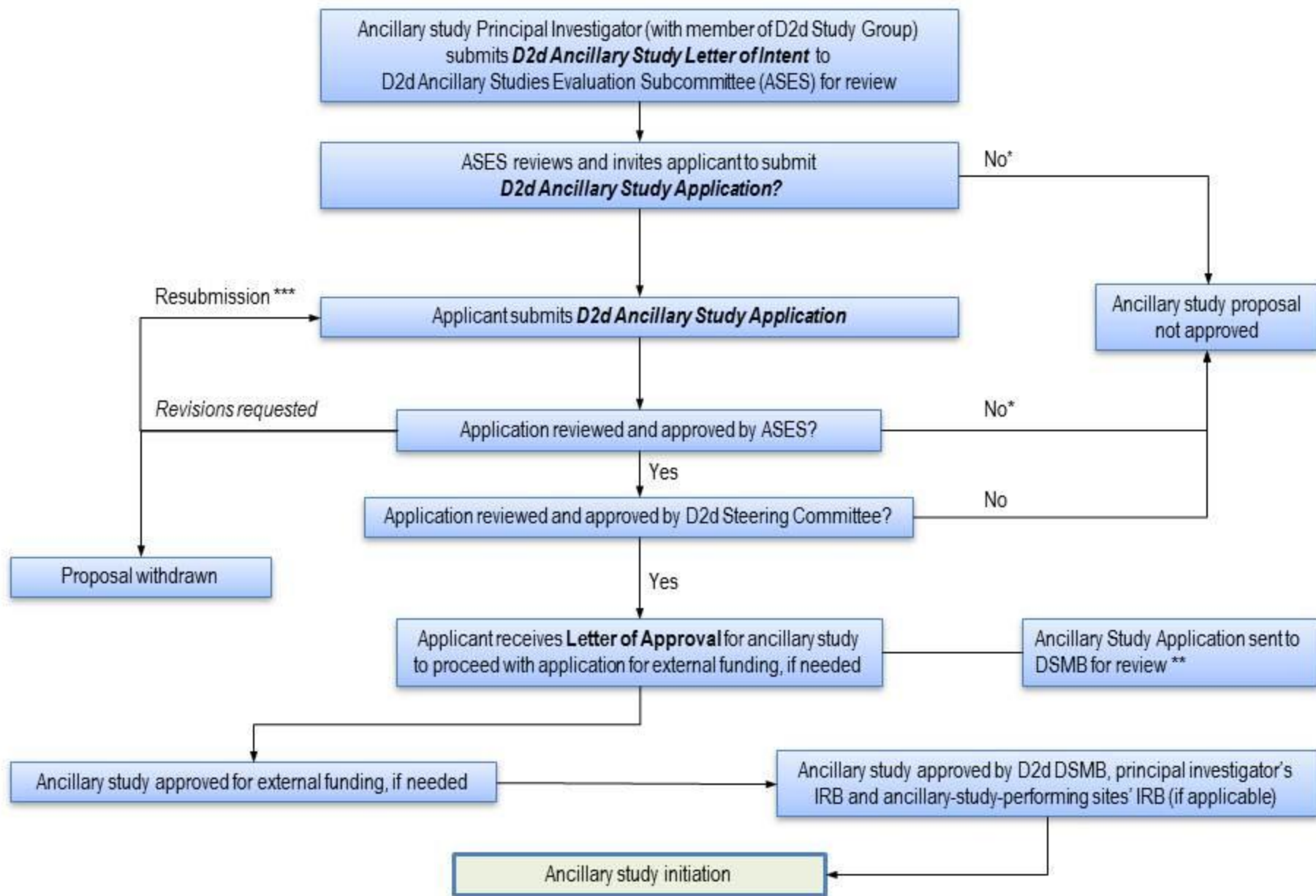
D2d Annual Meeting
November 17, 2014

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
- Sangeeta Kashyap
- Michael Lewis
- Taso Pittas
- Richard Pratley
- Philip Raskin
- David Robbins
- Cliff Rosen
- Myrlene Staten



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

Submissions – part 1

Title	Submission Date	Status
Pathways linking vitamin D and transition to diabetes	8/16/2012	Withdrawn by PI
Vitamin D supplementation and genetic modulation of transition to diabetes	3/18/2013	Withdrawn by PI
Effects of vitamin D on skeletal muscle mass and performance in pre-diabetes	3/29/2013	Under review by funding agency
Vitamin D supplementation to reduce vascular risk procession	4/4/2013	Not funded

Submissions – part 2

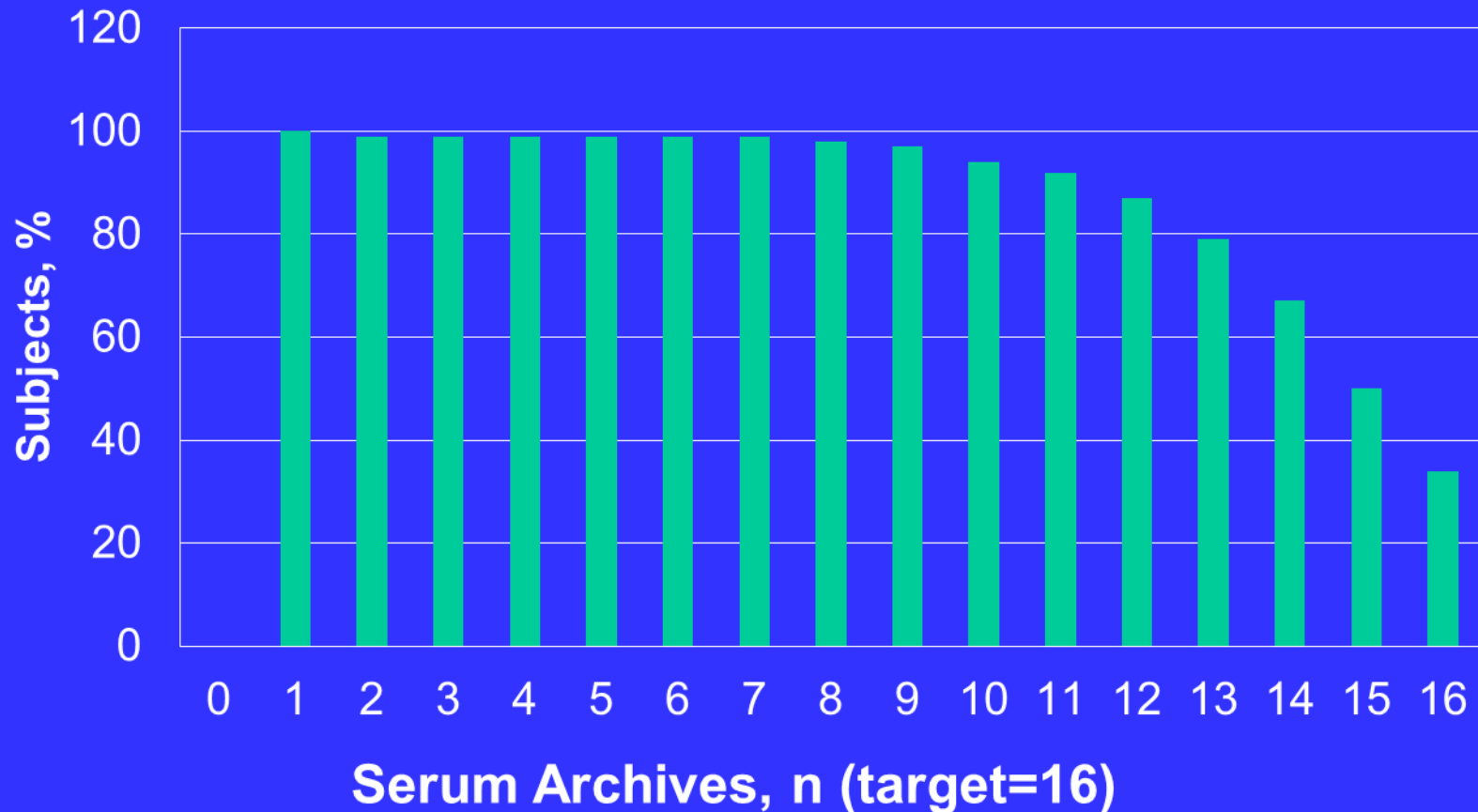
Title	Submission Date	Status
Effects of vitamin D supplementation on depression and mood	5/1/2013	Withdrawn by PI
Assessment of the (NDEP) GAMEPLAN toolkit in the D2d study	5/23/2013	Initiated
The vitamin D, type 2 diabetes, and gut microbiome (D2d-GM) study	10/22/2013	Under review by funding agency
Vitamin D supplementation and neuropsychiatric outcomes	12/21/2013	Withdrawn by PI

Submissions – part 3

Title	Submission Date	Status
Effect of vitamin D supplementation on risk for common cancers	2/10/2014	Under review by funding agency
Effect of vitamin D on androgen levels in prediabetic women	3/5/2014	Not approved
Tryptophan-kynurenine-NAD metabolism, inflammation, and type 2 diabetes mellitus	4/4/214	Reconsider
Contribution of free and total 25OHD in predicting progression to type 2 diabetes	5/5/2014	Under review by funding agency
Cognitive benefits of vitamin D in persons with pre-diabetes	7/16/2014	Under review by funding agency

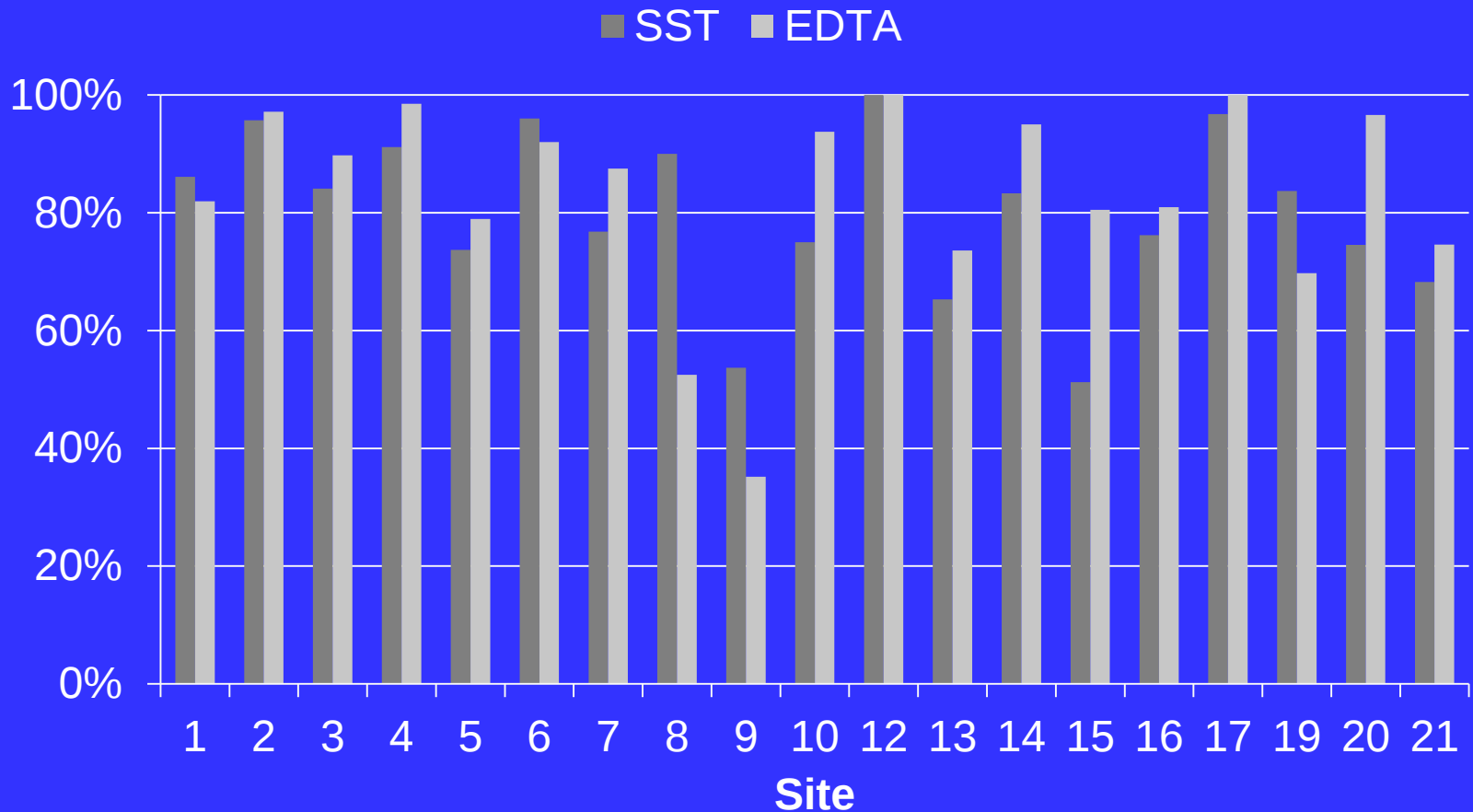
Repository Status

D2d serum archives collected at baseline



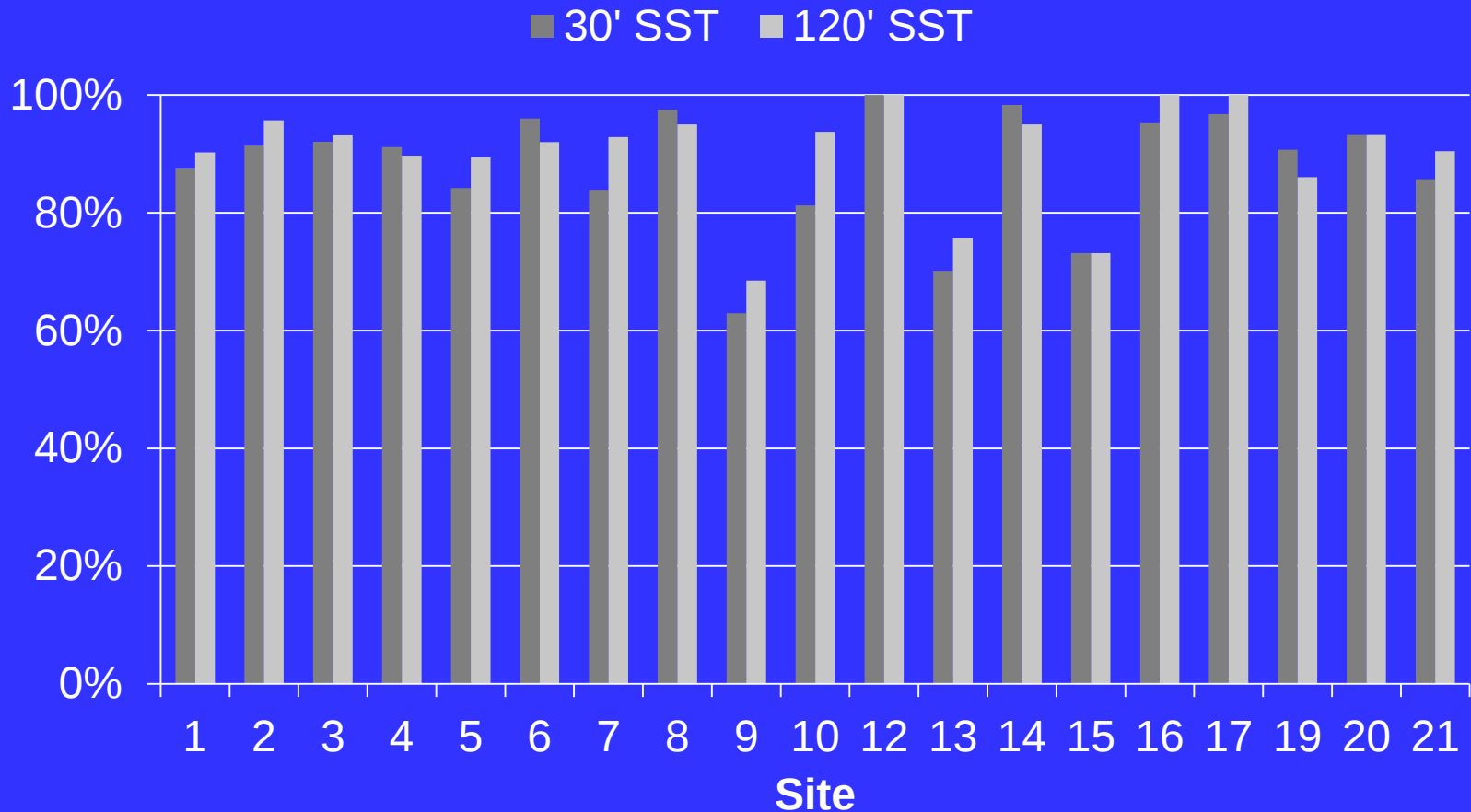
Baseline Repository Specimens

*% of participants with 13+ fasting cryovials
(out of 16 expected)*



Baseline Repository Specimens

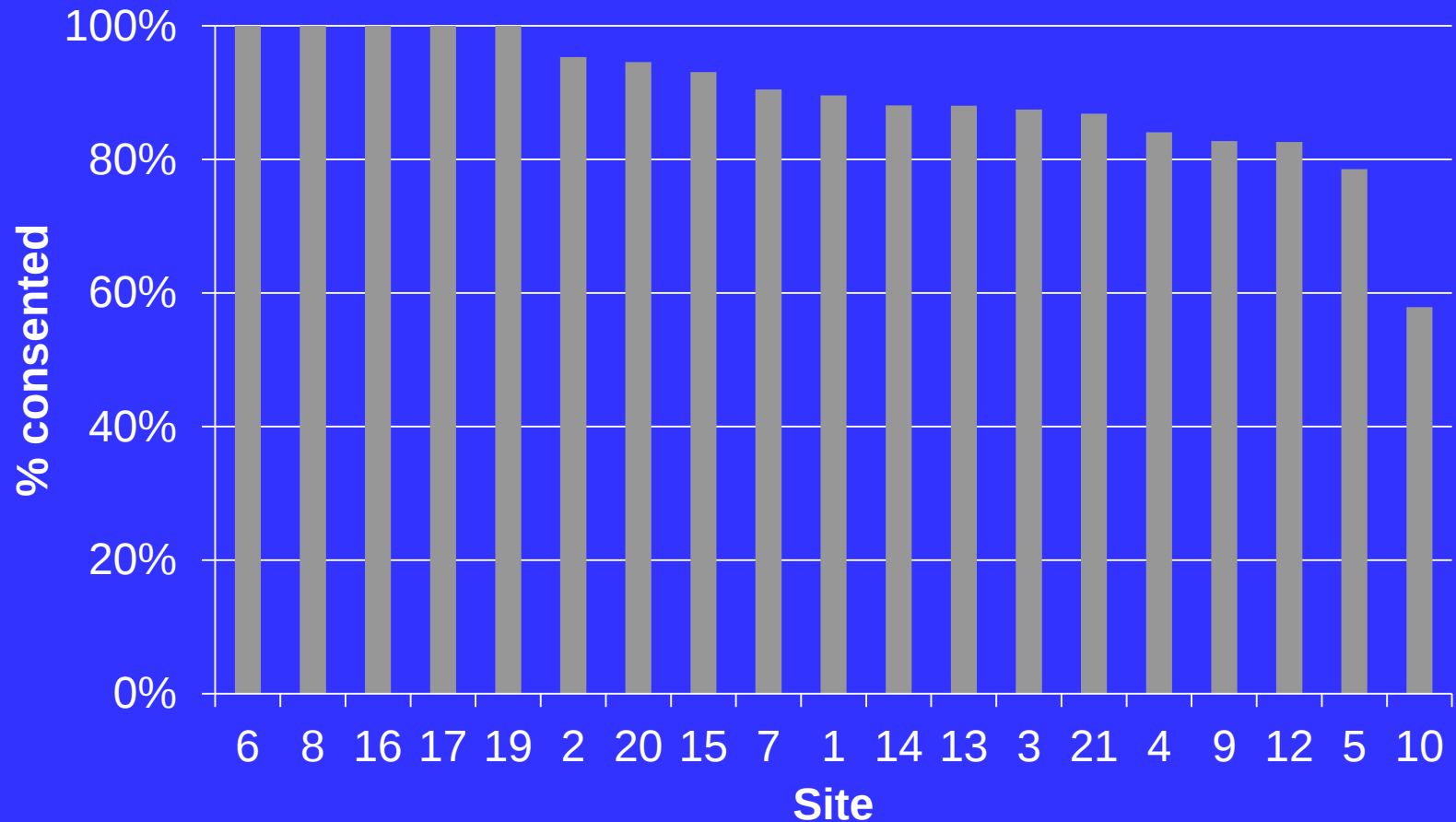
*% of participants with 3+ 30' and 120' cryovials
(out of 4 expected)*



Repository Acceptance Rates

- Number of participants eligible for randomization or randomized (as of 11/10) = 672
- Consented to biorepository = 599 (89.1%)
- Consented to DNA repository = 590 (87.8%)
- Consent to *both* biorepository and DNA repository = 588 (87.5%)

Biorepository Acceptance Rate by Site



DNA Repository Acceptance Rate by Site

