
CCSS Cohort Expansion: CCSS Follow-up Center

CCSS Investigator Meeting
Memphis August 24-25, 2007

Expansion Cohort

- 5 year survivors
- Dx 1987-1999
 - Originally estimated available: 31,700
 - Target # participants: 14,800

Expansion Cohort

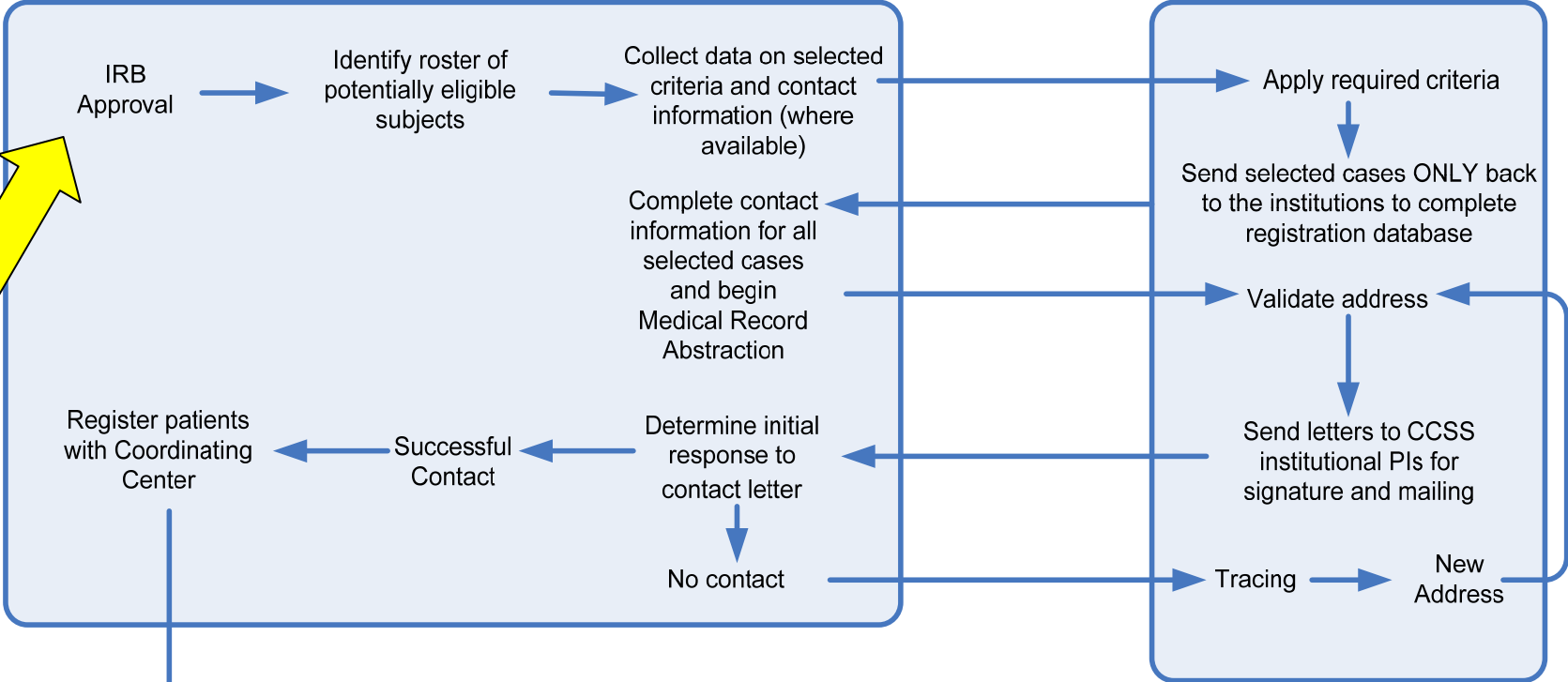
- Eligibility (same as original cohort)
 - Leukemia, CNS tumor, non-Hodgkin lymphoma, Hodgkin disease, neuroblastoma, Wilm's tumor, osteosarcoma, Ewing's sarcoma, rhabomyosarcoma, retinoblastoma
 - Treated at participating CCSS center
 - <21 years old at dx
 - Survival \geq 5 years from dx
 - English or Spanish speaking
-

Expansion Cohort

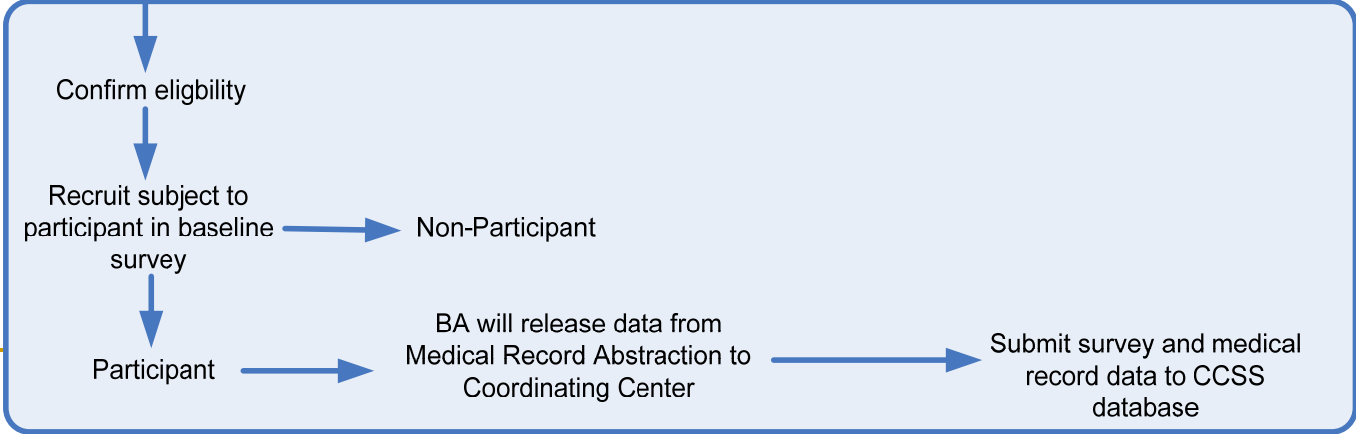
- Eligibility (not as original cohort)
 - Include retinoblastoma (subsequently dropped)
 - Restrict CNS tumors to PNET/medulloblastoma, ependymomas and gliomas
-

CCSS Institution

Business Associate



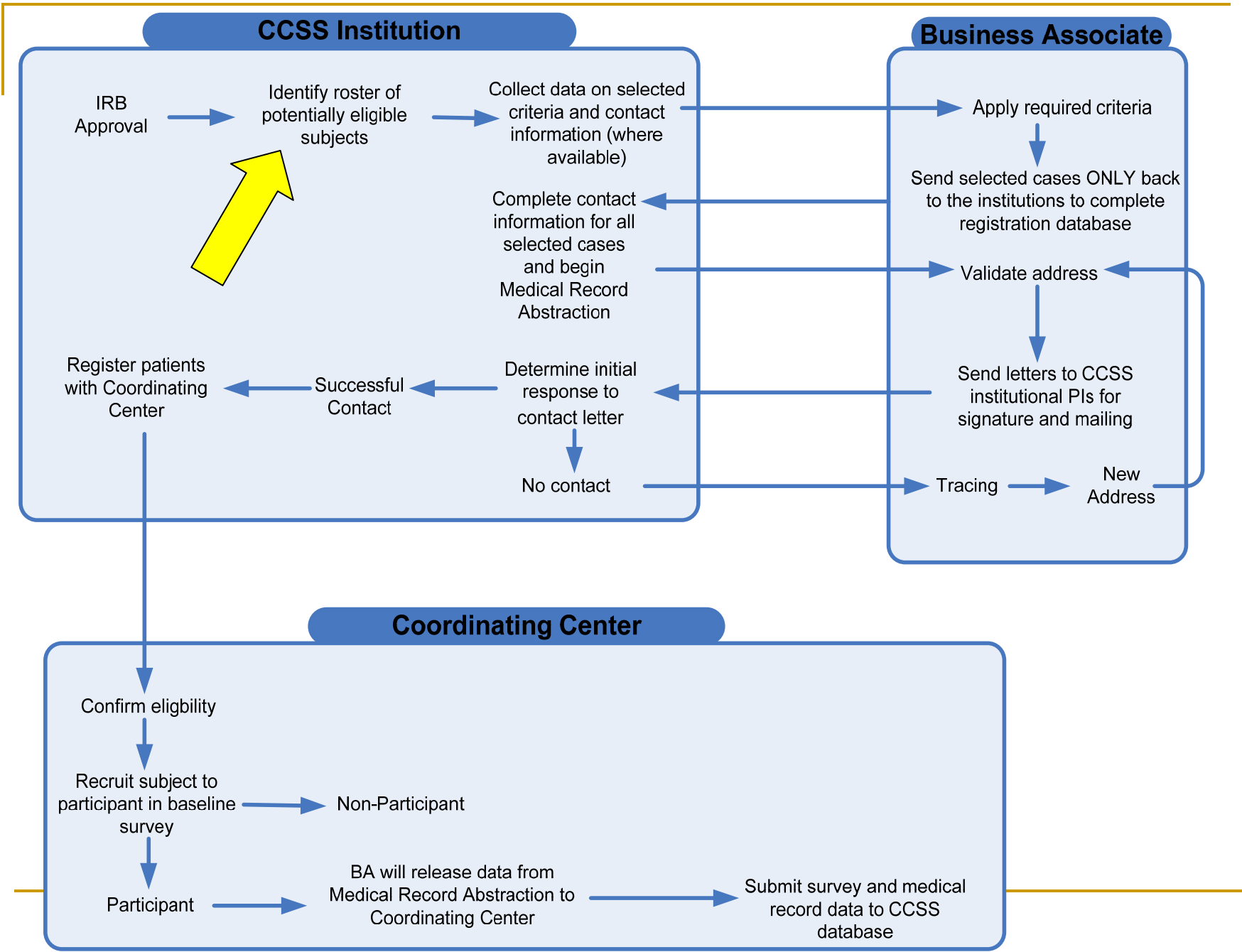
Coordinating Center



Progress to Date

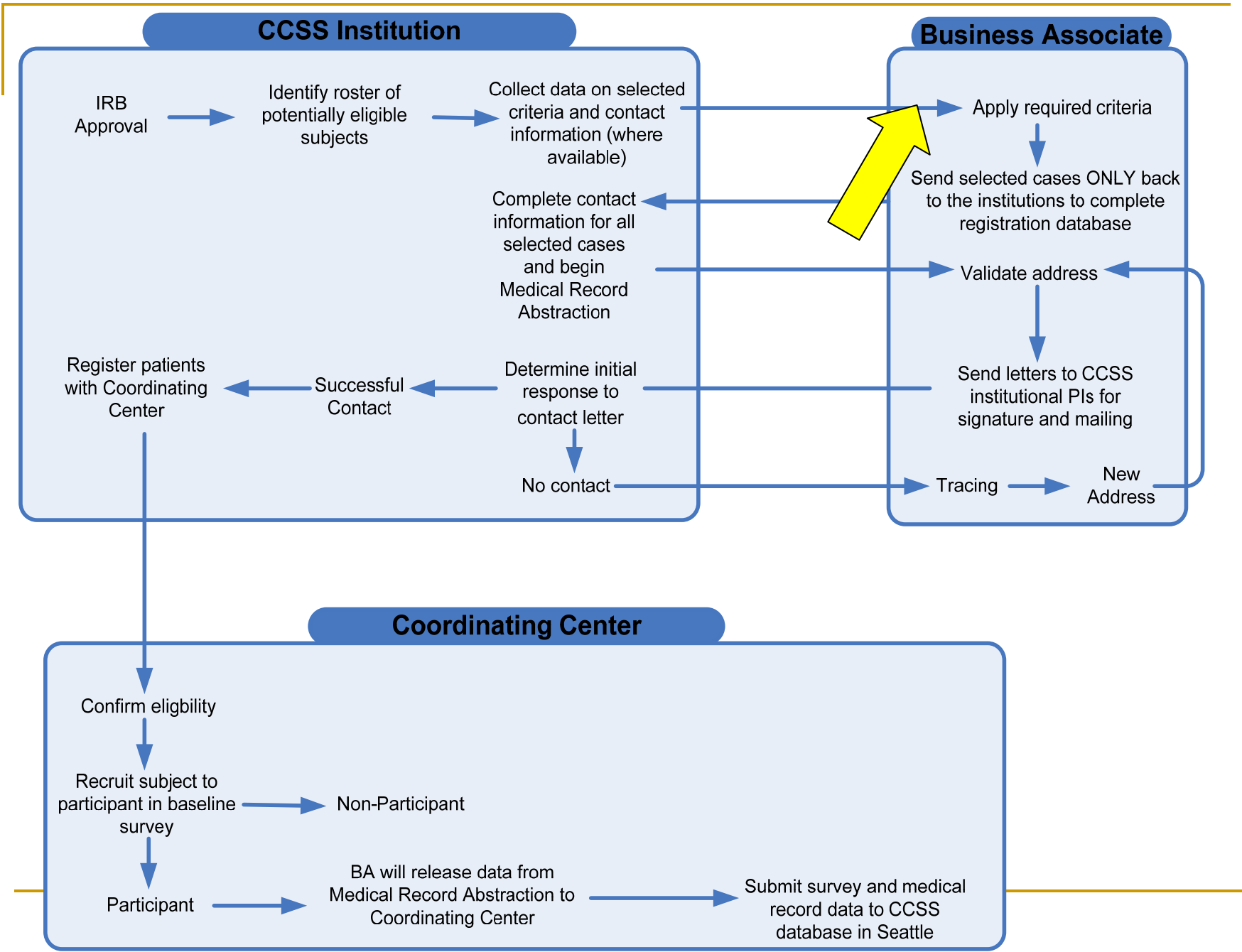
- Institutional human subjects approvals
 - 20 IRB waivers of authorization
 - 5 HIPAA business associate agreements
 - 1 both





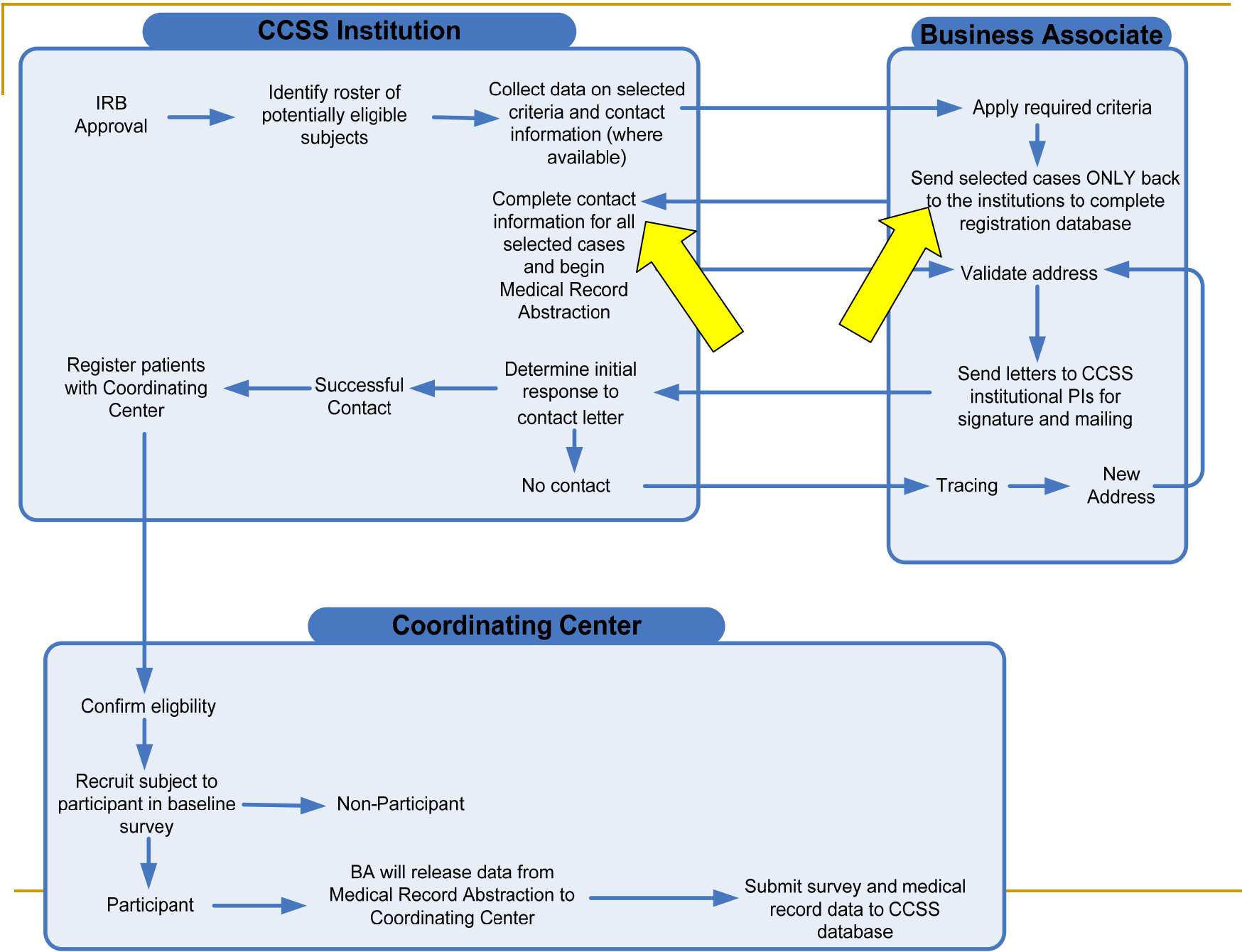
Progress to Date

- Institutions prepared rosters of eligible cases
 - Rosters submitted to Follow-up Center at USC
-



Progress to Date

- Statistical Center @ Fred Hutchinson prepared selection algorithm
 - Algorithm sent to USC to apply to database
-



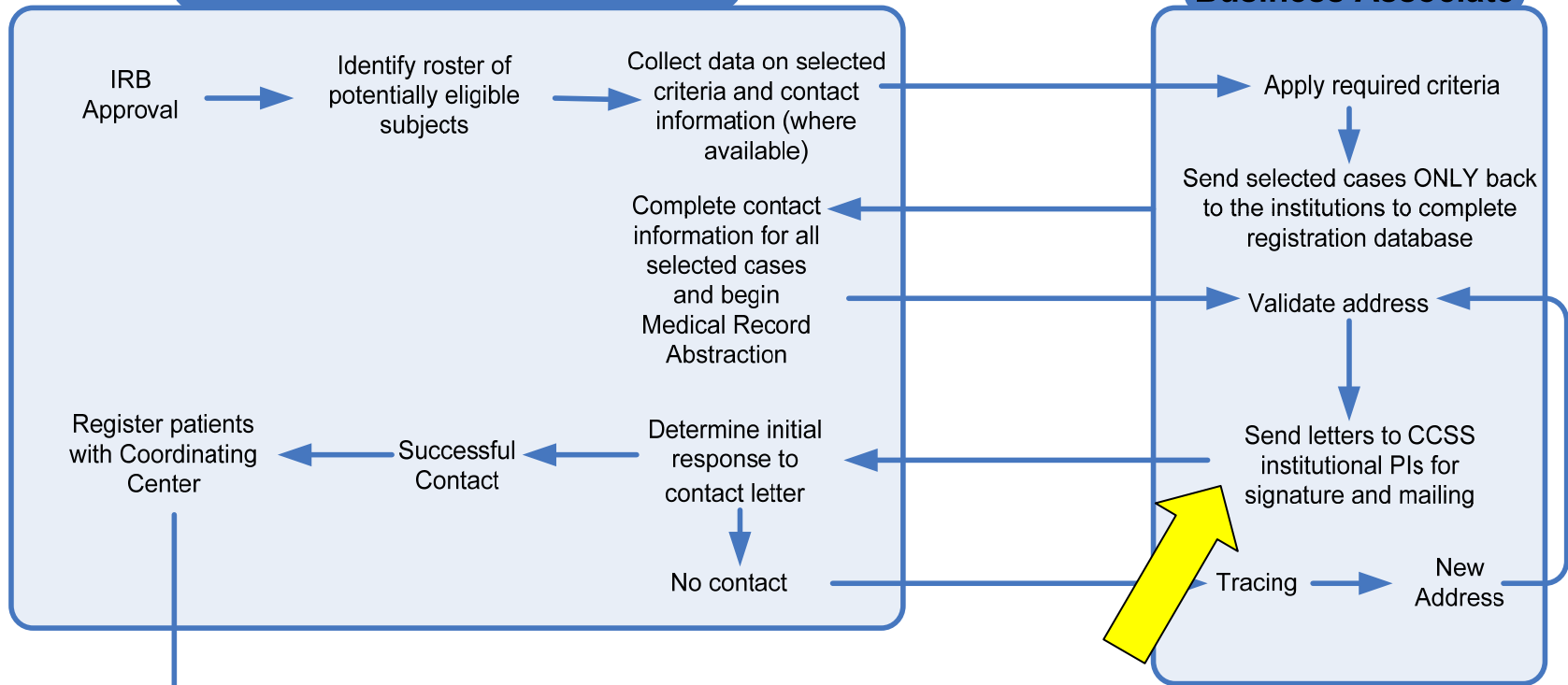
Progress to Date

- Total submitted cases: 26,093
 - Eligible cases: 25,095
 - Selected cases: 20,729
-

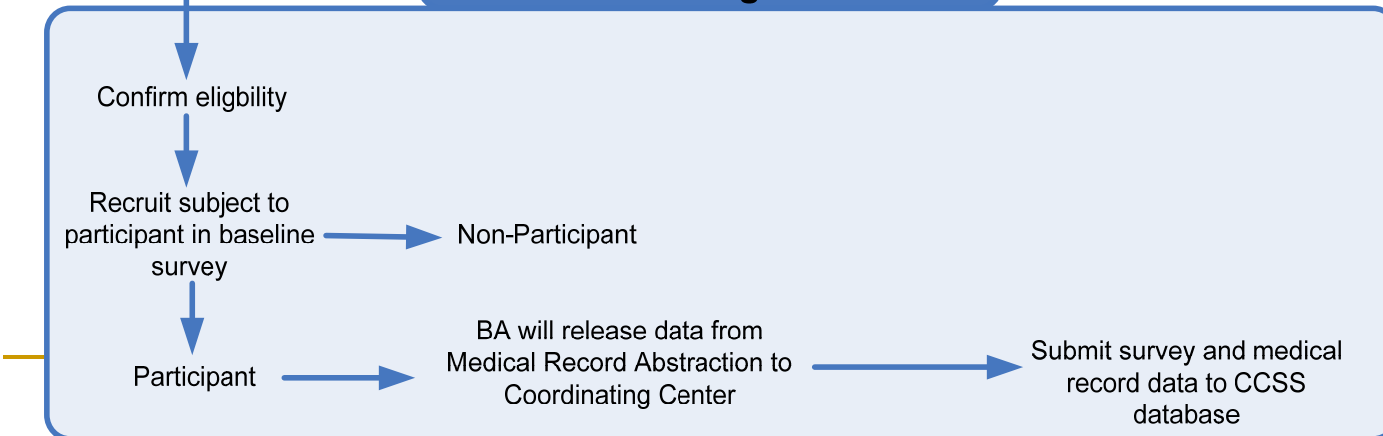
Next Steps

CCSS Institution

Business Associate



Coordinating Center



Registration Database

- USC has sent rosters back to institutions to add additional data: “Registration database”
 - St. Jude registration database complete
 - Test sample of cases
 - All other St. Jude cases
-

Recruitment Packets

- National change of address match
 - Recruitment packets*
 - Intro letter from institutional PI
 - Brochure
 - HIPAA form from institutional PI (2 copies)
 - Personalized, bar-coded
 - \$2 bill
 - Stamped return envelope
- *English and Spanish where indicated
-

Address Check

- National change of address match

Return Mail

- Undeliverable and address corrections will be returned by post office to institution
 - It is essential that these get sent to USC to capture most current address info
 - Signed HIPAA authorizations will be returned directly to USC
-

Follow-up for Non-response

- Follow-up packets
 - Slightly different follow-up letter signed by institutional PI
 - Brochure
 - HIPAA authorization forms (2 copies)
 - No \$2
 - Stamped return envelope
-

Follow-up for Non-deliverable

- Tracing and address correction
- Re-mailing of initial recruitment packet



Signed HIPAA Authorizations

- Copy retained at USC
- Originals mailed to institutions



Medical Record Abstraction Form

- Data sent to USC from secure web-based abstracting service
 - When HIPAA authorization is received
 - USC sends data to St. Jude
 - If HIPAA authorization is not received
 - USC creates de-identified frequency tables
-