CCSS: HIPAA-Compliant Recruitment

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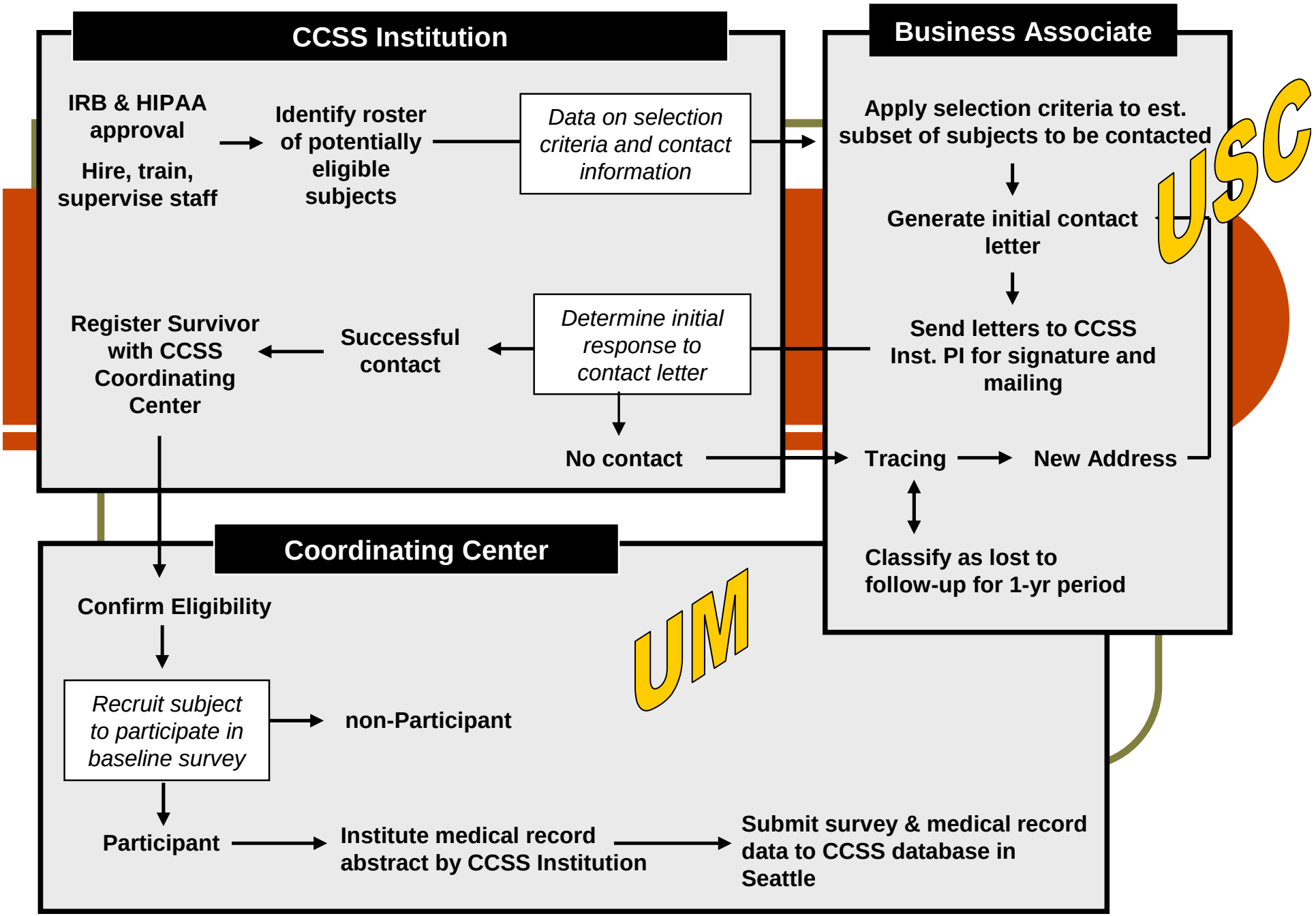

CCSS Institution
IRB & HIPAA approval
Hire, train, supervise staff
Identify roster of potentially eligible subjects
Data on selection criteria and contact information
Register Survivor with CCSS Coordinating Center
Successful contact
Determine initial response to contact letter
No contact
Business Associate
Apply selection criteria to est. subset of subjects to be contacted
Generate initial contact letter
Send letters to CCSS Inst. PI for signature and mailing
Tracing
New Address
Classify as lost to follow-up for 1-yr period
USC
Coordinating Center
Confirm Eligibility
Recruit subject to participate in baseline survey
non-Participant
Participant
Institute medical record abstract by CCSS Institution
Submit survey & medical record data to CCSS database in Seattle
UM

28 CCSS Institutions

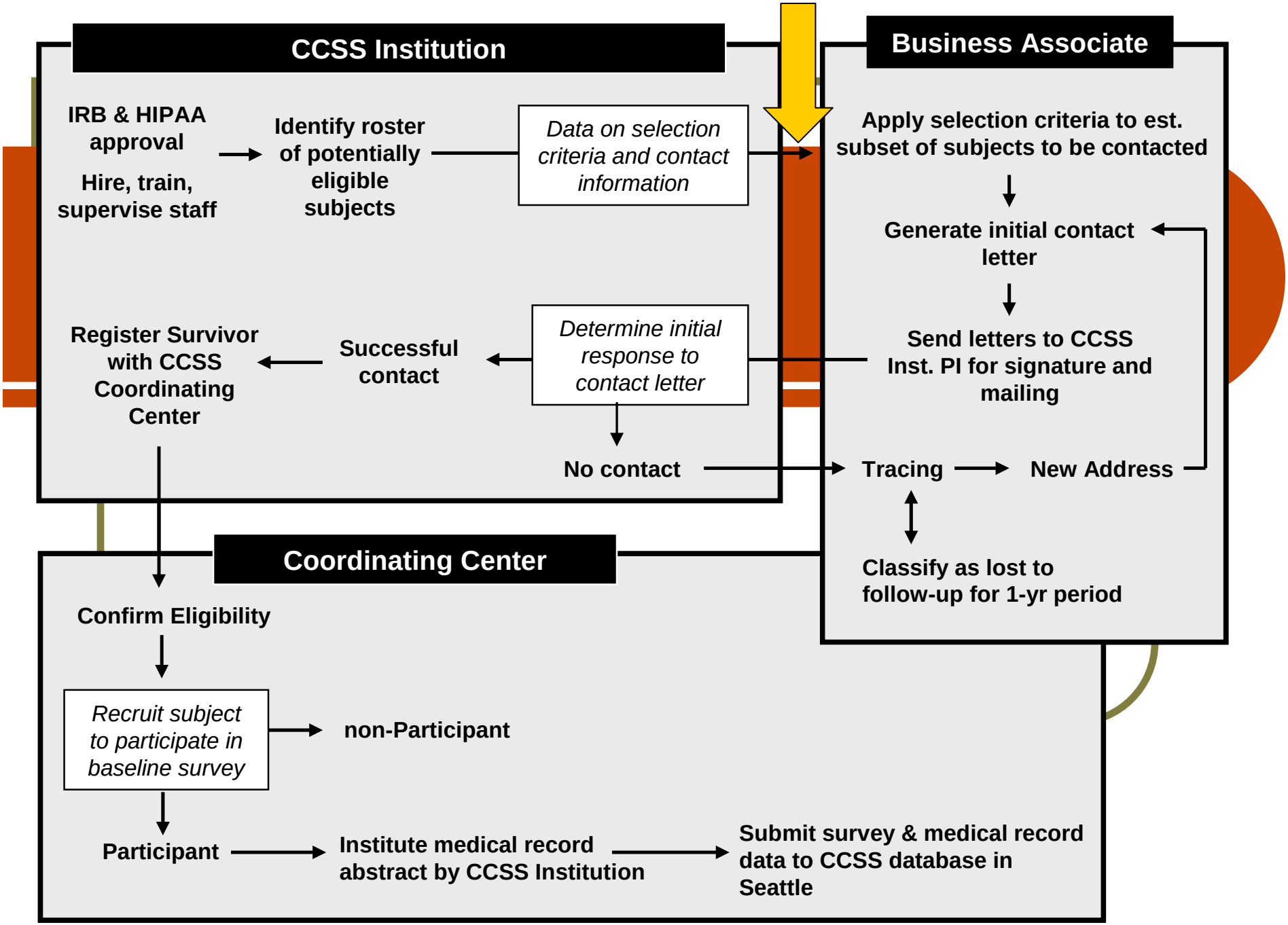
- Develop case finding and data abstraction methods
- Identification of potentially eligible cases
  - tumor registry, patient index, departmental databases
- Completed case registration forms sent to USC

USC

- Generate introductory letters/envelopes on letterhead of specific institution
- Returned to institutions for signature and mailing
- Letter introduces the study, requests consent to send contact info to Coordinating Center at UM
- USC performs locating of lost to f/u

But what about patient consent and HIPAA?

Figure D.1 Overview of Recruitment Procedures



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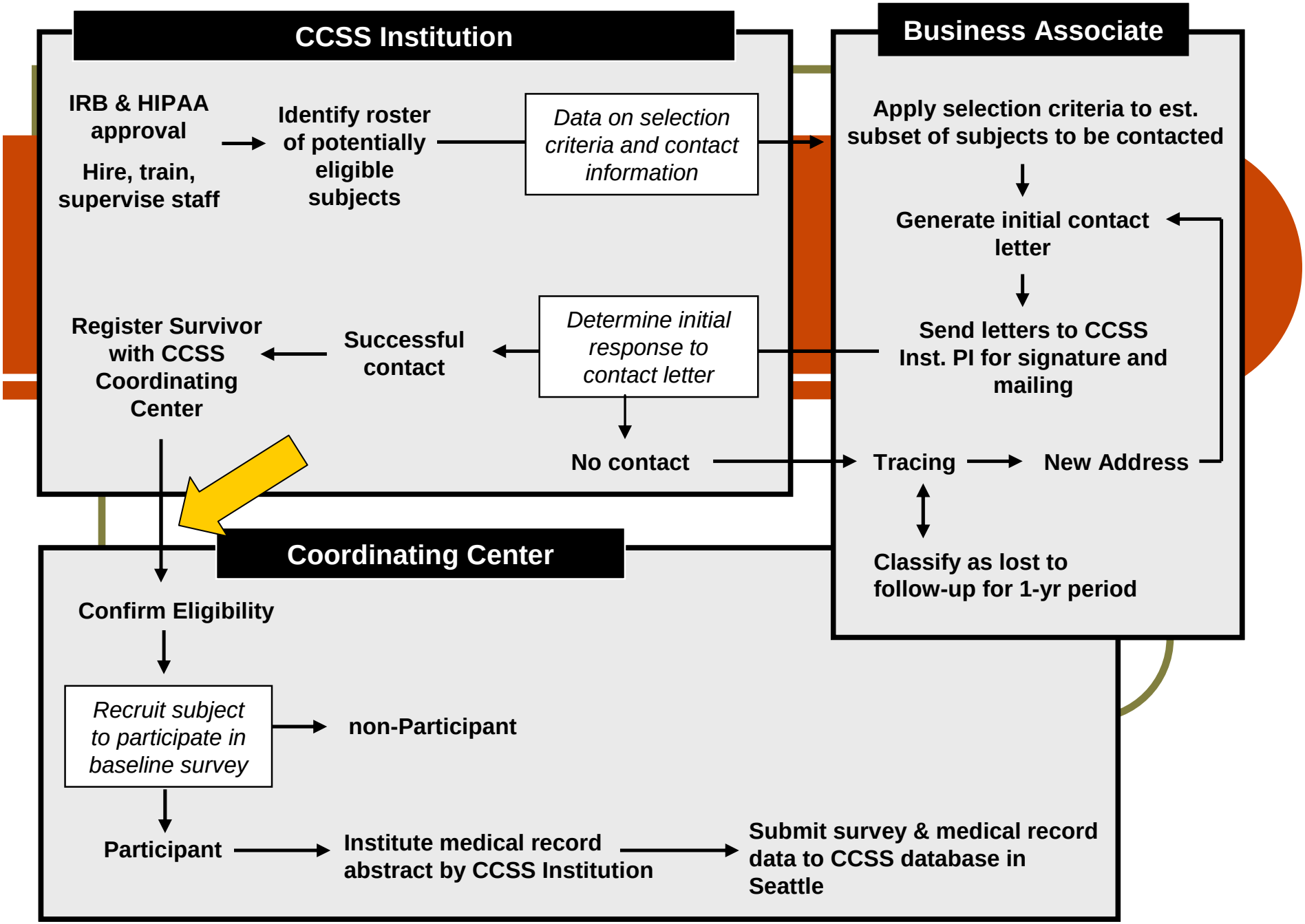

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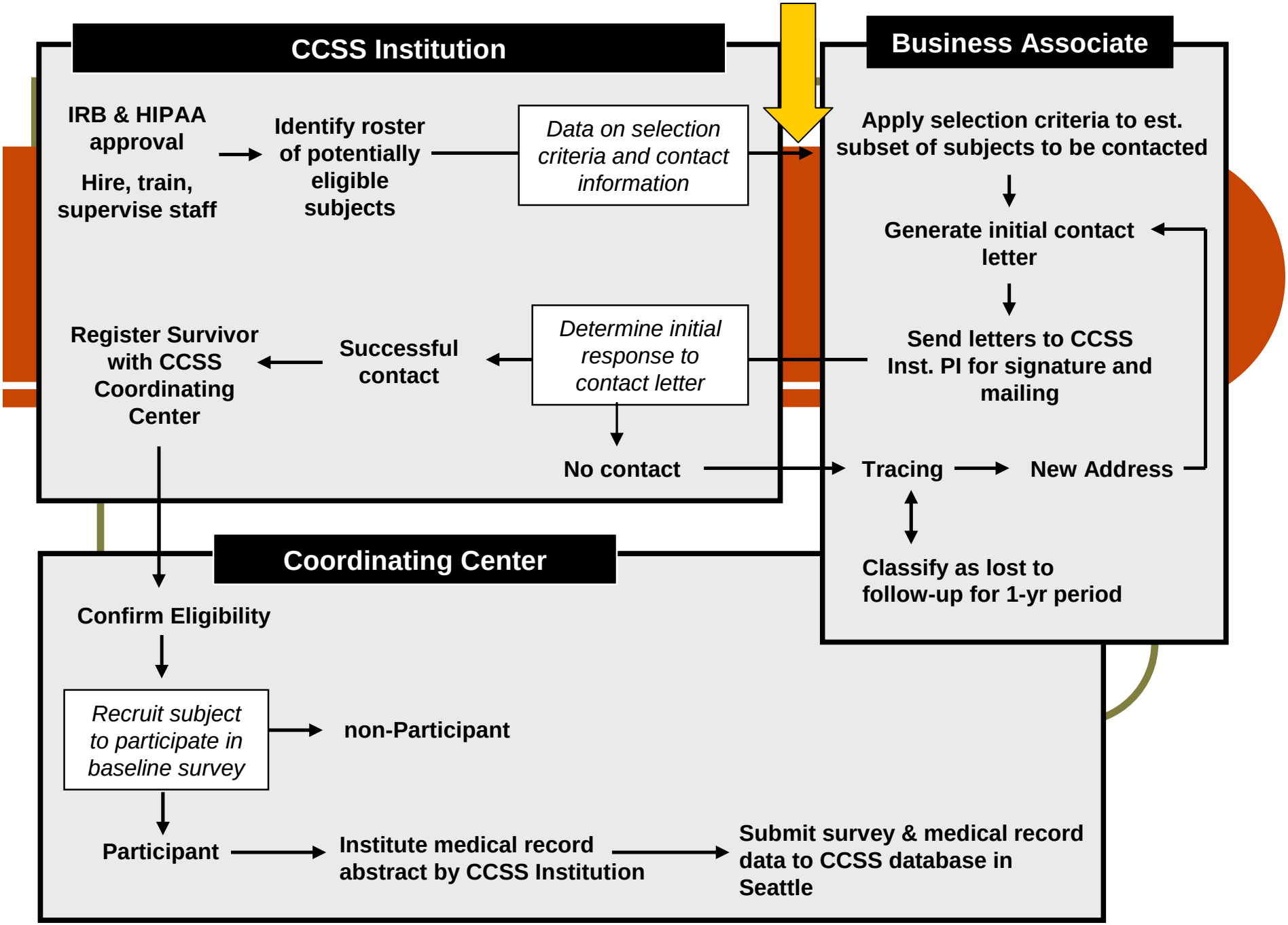

But what about patient consent and HIPAA for sending identifiers to USC?

- Release of patient identifiers and contact information from institutions is a HIPAA disclosure of protected health information (PHI)
- Options for HIPAA compliance
  - Institutions obtain consent
  - Business associate agreement (BAA)
  - IRB waiver of authorization for screening and recruitment

Institutions obtain consent

- Pros
  - No disclosure of PHI without authorization
- Cons
  - Lack clerical staff with appropriate expertise
    - Increases cost and time
  - Lack resources to check veracity of address information
    - Increases risk of breach of confidentiality
  - Lack resources to find current address information for lost to follow up
    - Creates bias in study population and results

Business associate agreement (BAA)

- Pros
  - Permits disclosure of PHI without authorization
  - Limits use and further disclosure
- Cons
  - Intended for activities related to payment or health care operations
  - Institutions have developed their own BAA language and often insist that theirs be used
    - Could require lengthy and costly negotiations with 29 institutions

IRB waiver of authorization for screening and recruitment

- Pros
  - Intended for research purposes
  - Permits disclosure of PHI without authorization
  - No institutional “canned” language
- Cons
  - Institutions may require their own review
    - Could require lengthy and costly negotiations with 29 institutions

IRB waiver of authorization for screening and recruitment

"Many research projects take place at multiple sites and require the use and disclosure of PHI…. The Privacy Rule does not require approval of a waiver of Authorization by both bodies because a covered entity may rely on a waiver by any IRB"

Source: Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, Department of Health and Human Services, NIH Publication Number 03-5388

What does an IRB waiver of authorization require?

- IRB determines that
  - Use or disclosure of PHI involves no more than minimal risk to privacy
    - Plan to protect identifiers from improper use and disclosure
    - Plan to destroy identifiers
    - Assurances that PHI will not be reused
  - The research could not be practicably conducted without the waiver
  - The research could not be practicably conduced without the PHI

Recommendation for CCSS

- Obtain IRB waiver of authorization from USC
- Provide waiver and HHS guidance on reciprocity to clinical institutions and ask that it be honored
- USC
  - prepares patient contact/consent materials to be sent by clinical institutions
  - locates lost to follow-up
- HIPAA compliant consent is obtained prior to transmission of data to UM