



Virtual Specimen Locator Network

2001 Shared Pathology Informatics Network (SPIN)

Expedited review by HMS IRB of feasibility study

- **Developed and tested technologies to address HIPAA requirements**
 - scrubbing program
 - limited data set
 - anonymous data set
 - no ongoing aggregation of data
- **Worked with IRBs (HMS, Partners, BIDMC, CH) to design approach to potential distribution of specimens**



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MAY 2004

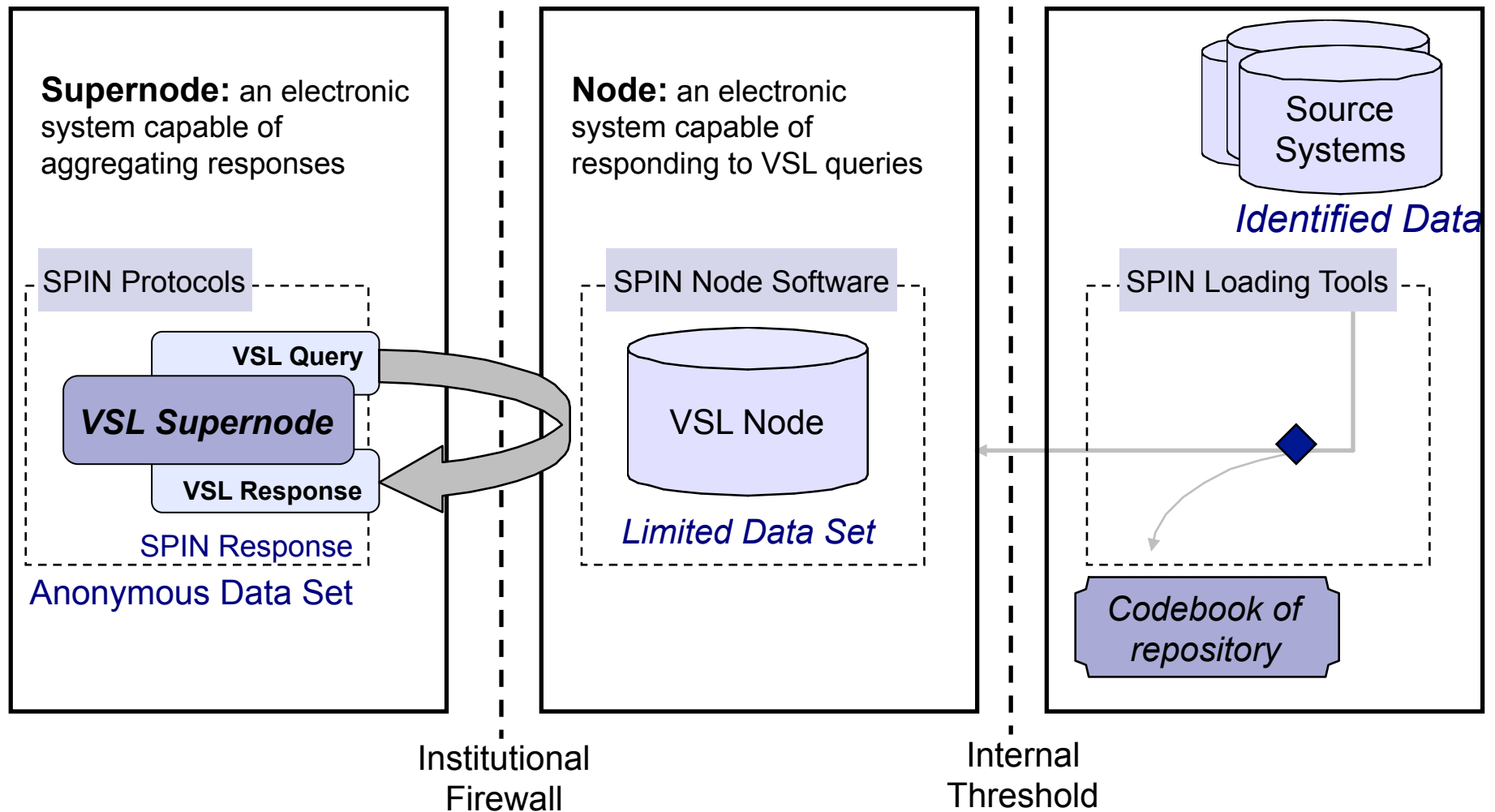
- HMS IRB staff and Harvard-affiliated hospitals' IRB leadership and pathologists met with OHRP and NCI

Conclusions

- Approved concept of de-centralized model -- **VSL** -- to facilitate specimen identification and location
- Agreed by HMS and Harvard-affiliated hospitals that HMS IRB would do review of the VSL network model prior to launching it at hospitals

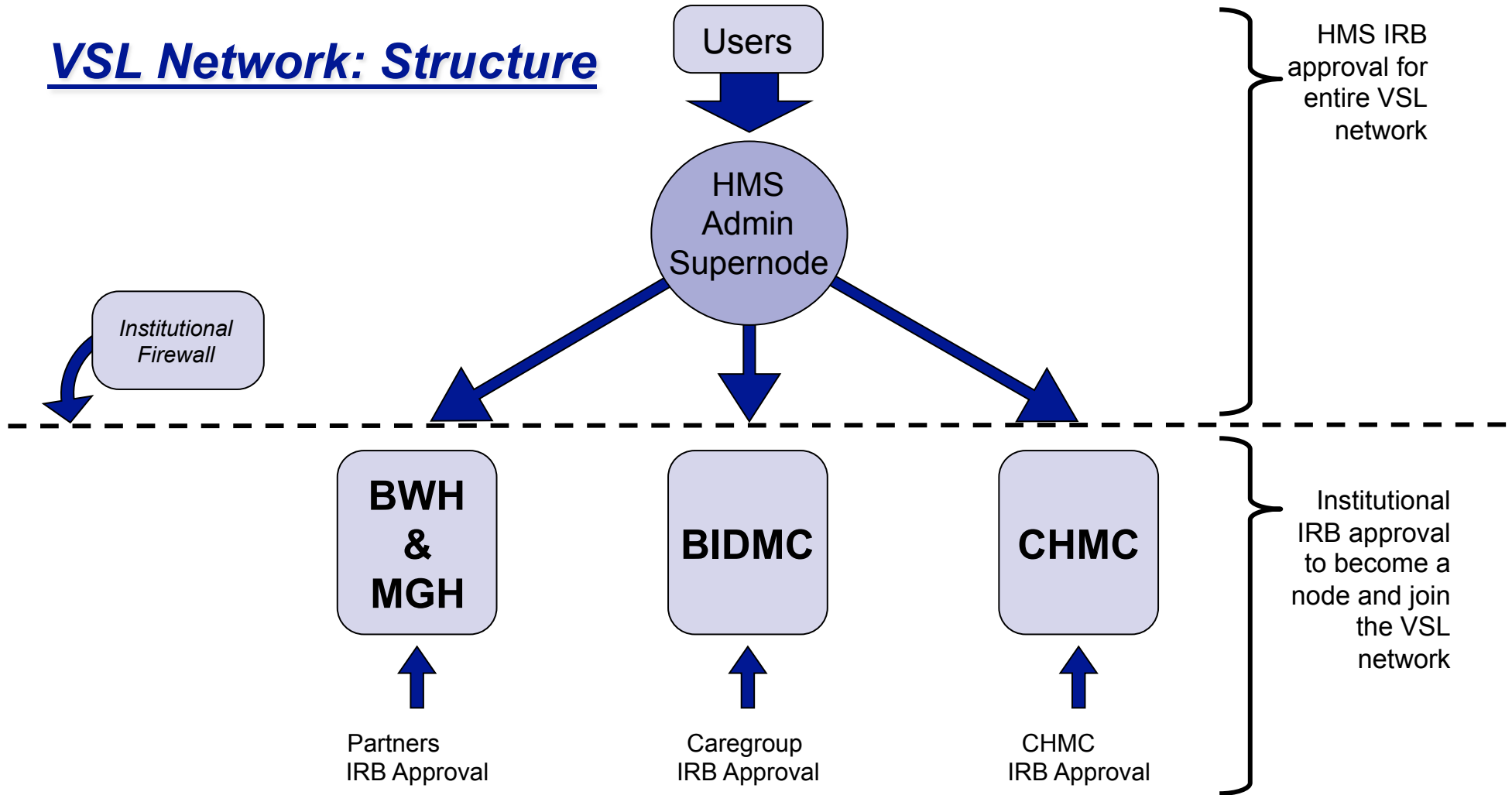
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Data Flow and Tool Sets: HIPAA compliance via programming, data location, and firewall protection



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VSL Network: Structure



Following Hospitals established rules for its repositories per se

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How it would work:

Step 1

Harvard researcher enters through web browser

HMS eCommons
credentialing of
researcher

Compose Web Query

Response in
aggregate data

Step 2

Researchers' local IRB reviews study protocol requiring specimens/clinical information, etc

Step 3

Repository's local IRB, as necessary, review request or allows repository to grant access according to established access business rules (apparently by local IRB)



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Principles for Operating Network

- Each institution is responsible for compliance to its internal human subjects protection structure and for HIPAA
- Each repository in the VSL network must have prior approval from its local IRB to engage in the activities of the VSL network
- Each repository must comply with the VSL network guidelines and use VSL-approved software to continue its involvement in the VSL network.
- Distribution of specimens and/or information will be done at the discretion of, and in accordance to, the participating repository's access business rules as well as the host institution's IRB and research governance policies.
- An Oversight Committee to address any potential issues between repositories and users. Current Oversight Committee to comprise chiefs of surgical pathology services in each of 4 hospitals. As non-pathology department repositories join the VSL, composition of the VSL Oversight Committee to be reconsidered.