Using Technology to Strengthen Human Subject Protections

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Funding and Development

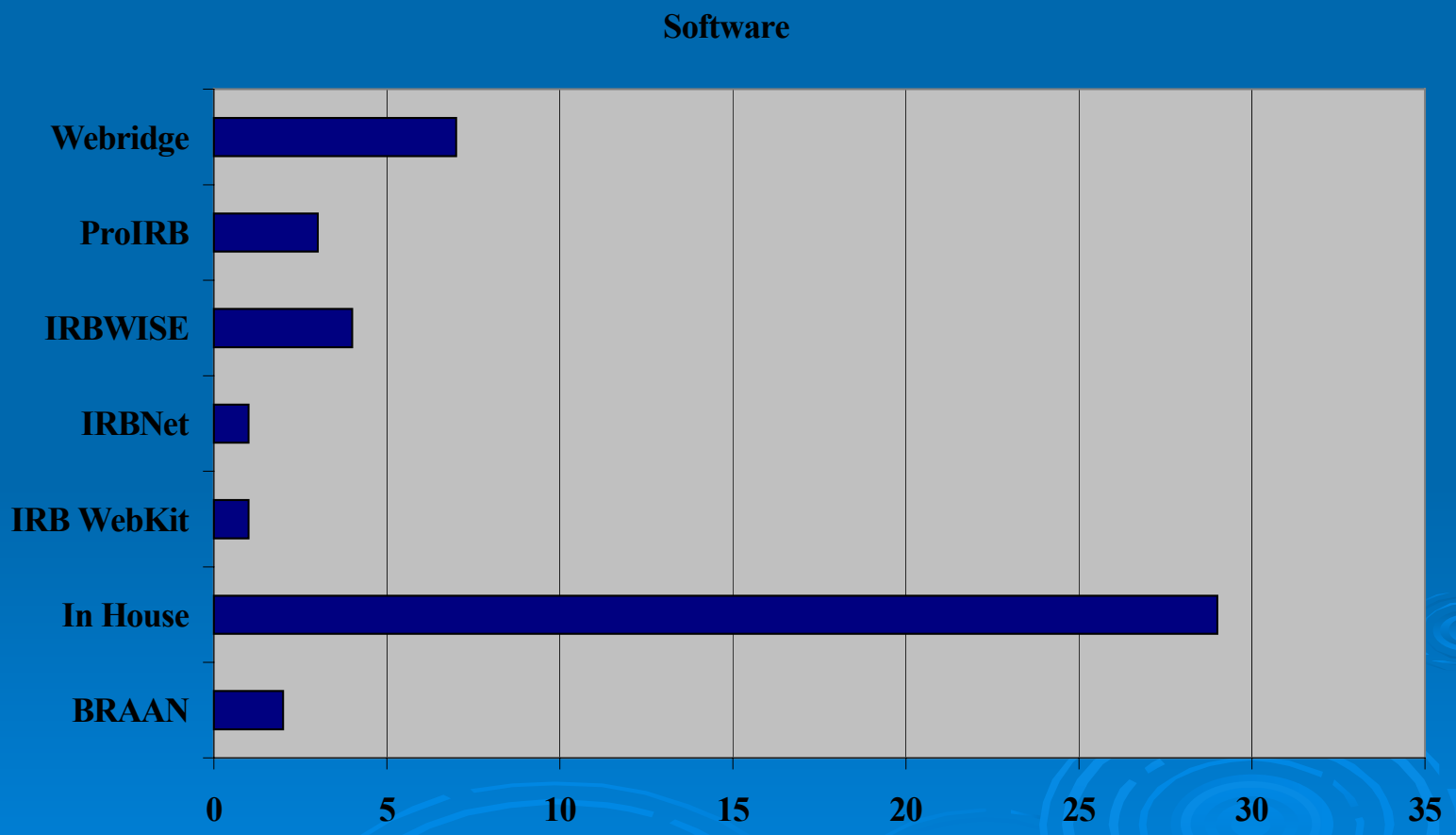
In 2002, the Human Studies Committee received an NIH grant that provided funds to:

- Authenticate users,
- Create the framework for total electronic submission,
- Verify that users of the system have completed education requirements, and
- Develop an electronic system for submission of SAEs.

Determining a vendor:

- Consultant (WUSM choice)
- In-House Task Force
- RFA

Human Subjects Research Enhancement Program (HSREP)



NIH does not endorse any vendor.

Additional Funding

In 2003, the IRB received a second grant from the NIH that is providing funds to:

- Develop an electronic system for all remaining IRB activities, and
- Create a mechanism for communication and transfer of information between WUSM internal reviewing committees.

Initial Grant Goals

1. Authenticate users
2. Verify Completion of Education Requirements
3. Develop Electronic Screening Tool for Serious Adverse Event Reports

AIM 1: Designate and Authenticate Users

- PeopleSoft (HR Database) provides personnel data.
- PI designates who will manage the data within a particular protocol.
- Faculty and staff are authenticated by using an encrypted login and password.
- The system identifies them and determines their level of access.

Aim 2: Verification of Education

- System will record key participants' completion of basic and on-going education.
- Research will not be approved until education requirements are completed.

Aim 3: E-Submission of SAEs

Automatically screens SAEs and routes them based on:

- Where event occurred (WUMC vs external),
- If event increases risk to participants,
- Whether event resulted in modifications to the consent and/or protocol.

Historical Perspective

- 1991 SAE Reports 43
- 2003 SAE Reports 11,020

Problems with External SAE Reports

Insufficient data

- no denominator
- missing medical information

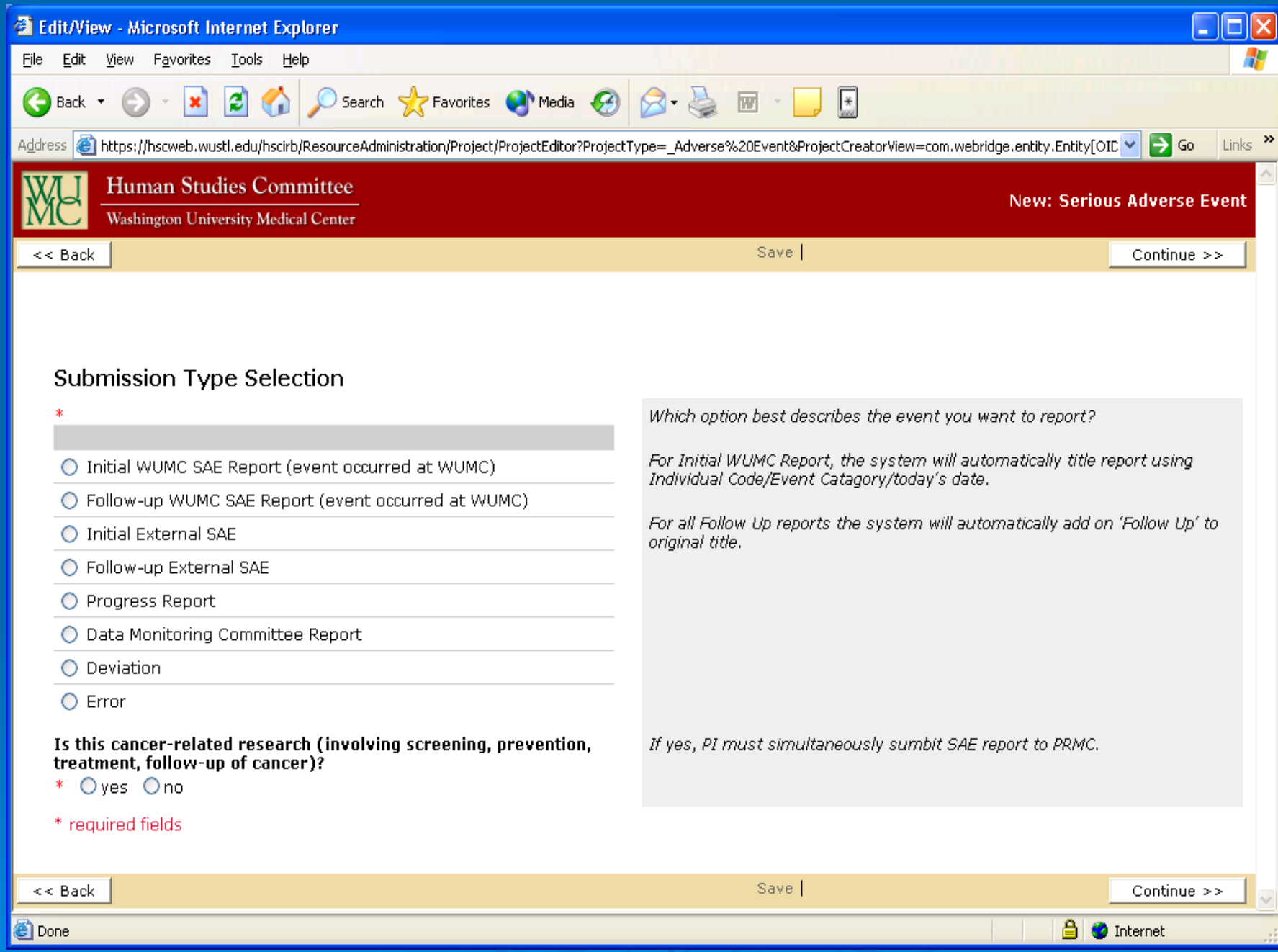
Blinding

- IRB reviewer lacks knowledge; DMC has knowledge and is qualified to evaluate it.

IRB should focus its resources on tasks that will protect human subjects and rely on DMCs to conduct an in depth review of SAEs.

Screening Tool

- Determines whether event is reportable per federal regulations.
- If, after screening, event does not qualify as an SAE, PI is informed of such but may still submit if he or she believes the IRB should review the event.
- When an event is reportable, the system queries the PI for other decision-influencing data.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Go Links
Human Studies Committee
Washington University Medical Center
New: Serious Adverse Event
<< Back
Save |
Continue >>
Submission Type Selection
*
Initial WUMC SAE Report (event occurred at WUMC)
Follow-up WUMC SAE Report (event occurred at WUMC)
Initial External SAE
Follow-up External SAE
Progress Report
Data Monitoring Committee Report
Deviation
Error
Which option best describes the event you want to report?
For Initial WUMC Report, the system will automatically title report using Individual Code/Event Catagory/today's date.
For all Follow Up reports the system will automatically add on 'Follow Up' to original title.
Is this cancer-related research (involving screening, prevention, treatment, follow-up of cancer)?
* yes no
If yes, PI must simultaneously sumbit SAE report to PRMC.
* required fields
<< Back
Save |
Continue >>
Done
Internet

Electronic Submission Process

__ Initial WUMC SAE Report
__ WUMC SAE Follow-up Report
__X__ Initial External SAE
__ Follow-up to External SAE
__ Progress Report
__ Data Monitoring Committee Report
__ Deviation
__ Error

PI's Responsibility

- "As the Principal Investigator, you are responsible for reviewing the protocol related report. Based on your medical expertise, you are responsible for taking appropriate action(s) required to protect research participants."

1. Does anything stated in the SAE Report increase the risk to the subject population?

2. Does the SAE in the Report provide new information, e.g. unanticipated event, and is it of such magnitude and/or frequency that it requires modification of the consent?

- If yes, . . . (*IRB review will be conducted.)*
- If no, . . . *(filed)*

If yes, PI will indicate action(s) for IRB's consideration

_ suspending study enrollment
X revising the consent form
_ composing a letter to participants . . .
_ modifying study
_ other

Attachments

- Supporting documentation will be submitted to the IRB as an attachment for all SAE reports.
- Revised consent forms and/or protocols
- Amendments

Impact on IRB Procedure

- IRB professional staff will review internal SAEs and external SAEs that increase the risk to participants.
- Electronic screening of SAEs will significantly decrease the IRB member's and staff's workload!

Lessons Learned

Dedicated Staff is Essential

- IRB knowledgeable project manager
- Institutional IT ***staff***

Steps to Success

- Meticulously map workflow
- Involve users **early**
- Pilot groups must **have** scanners
- Limit initial deployment

Summary

Technology has great potential to increase the efficiency and effectiveness associated with the responsible conduct of research.

Investigators and regulatory offices will have on-line, current information available at all times.

Developing and implementing an e-submission program is challenging but is being successfully implemented by IRBs across the country.