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Software applications offer a number of significant advantages to institutions that review many research protocol applications per month including:

- A traceable record of the process for each
- Electronic filing of all pertinent materials
- Consistency of the review process
- Reduced administrative workload for research committee coordinators

However, available software solutions are typically expensive, may not be customizable to meet specific institutional needs, and may represent a potential liability with respect to long-term support (custom third-party software). Five years ago, Environmental Health and Engineering, Inc. (EH&E) began utilizing Microsoft SharePoint as a platform for the development of environmental health and safety (EHS) and biosafety applications to support EHS and biosafety programs in several large research institutions managed by EH&E. We have recently expanded its use to Institutional Biosafety Committee (IBC) program management.

Microsoft SharePoint is a web-based collaboration platform designed to allow project teams to design customized project sites where they can share documents and information, and track project progress. We have found it highly effective at managing program documents and data for very complex programs, as well as communicating program status in an organizational format consistent with the needs of each institution. SharePoint is also gaining popularity, with SharePoint servers (and consequently SharePoint Information Technology support) found in most research institutions. Therefore, SharePoint represents a low-cost (and common) potential resource for many applications. Here I will talk specifically about a SharePoint IBC application, but the same system could include Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) functionality.

Three primary features are associated with SharePoint that are critical for this application: its ability to utilize web-based data-entry forms to collect and disseminate information, its inherent system of permissions allowing levels of user access, and its ability to automate workflow processes. In our experience, the primary benefit realized with the application is the automation of administrative tasks associated with the IBC protocol approval process. Automation frees the IBC administrator from the myriad of tasks associated with continuous oversight, which is necessary to keep the process moving and participants informed. And in every case the automation resulted in significantly fewer days from receipt to approval, thus a more efficient review process. But we also found that while the major steps of the review process are quite prescribed, many variations exist due to cultural differences within each institution. The ultimate success of the application depends upon its ability to mirror (or improve if necessary) the process in place.

Development of the application begins with careful modeling of the actual review process used within the institution. We find creation of a flow chart a useful start, and then drilling down to determine the exact sequence of events comprising each stage or control point in the process (Figure 1). The control points are breaks in the process at which the biosafety officer (BSO) reviews the previous step and makes a manual determination as to the next step in the process. The result is a sequence of process stages with detailed information concerning the input required, the personnel involved, the timeframe required for action, and the system response for all possible actions. Permissions associated with each stage are also determined during this process.

The institutional forms used to submit research applications, amendments, annual reviews, etc. are then transferred to web format (typically from Microsoft Word) via InfoPath (a Microsoft form-generation program). Data entry and viewing are performed in the original format, making it easy for reviewers to adapt to the electronic forms. Forms are then associated with additional data fields required for protocol review as determined in the modeling phase. For example, comments fields may be added to track reviewer comments, defined control points are choices in a “Stage” field, and a field may be added to collect the names of one or more designated reviewers (Figure 2). Permissions are used to determine what fields researchers, reviewers, and the BSO can view or edit as part of this effort.

E-mail alerts and rules can be developed and associated with the individual workflows comprising each stage in the review process. For example, selection of an “Initial Review” stage may trigger e-mail alerts to all committee members requesting their input as to whether a protocol requires a full committee review within 4 business days. When either a committee member makes this recommendation or the deadline is reached, the BSO receives an e-mail notice that the stage is complete. As
**Figure 1**

IBC Demonstration Workflow Diagram

- **Application Submitted by PI** → **BSO receives alert, reviews application**
  - **Is application exempt?**
    - **Yes**: BSO changes status to “Exempt.” Alert goes to PI saying it is exempt (based off of “Exempt” view.)
    - **No**: **Does application involve rDNA or novel infectious agent?**
      - **No**: **Designated Review: BSO** changes status to “in Designated Review” and assigns reviewers. Reviewer(s) and IBC Chair receive alert (based on “Designated Review” view).
      - **Yes**: **Full Committee Review: BSO** changes status to “Full Committee Review”. BSO/Chair appoints Primary and Secondary Reviewers. Alert goes to assigned reviewers to review application.

  - Reviewers make comments in “Reviewer Comments” field, check box indicating “Review Complete.” BSO gets alert once box is checked, changes “Status” to: Approved, Pending Approval or Full Committee Review

  - **If Full Committee Review, goes into Full Committee Review Process**

  - Approved: PI gets alert (based on “Approved” view).
  - Approved Pending: PI gets alert (based on “Approved Pending” view).

  - **Committee reviews at meeting. Based on meeting vote, BSO changes “Status” to: Approved, Pending Approval, Tabled, Withdrawn.**
    - **Tabled: PI gets alert (based on “Tabled” view).**
    - **Withdrawn: PI gets alert (based on “Withdrawn” view).**

  - BSO/Chair build agenda by checking box indicating “On agenda” for applications under review. One week prior to meeting, full committee receives alert to review applications on agenda.

noted previously, the more accurately these workflows follow the existing internal process, the less the resistance encountered by committee members and researchers.

The final stage in application development is the construction of dashboards for each of the represented groups (e.g., researchers, committee members, BSO). These dashboards are designed to show each group information pertinent to its role in the review process. Metrics are often associated with the dashboards to measure improvements in program efficiency (e.g., time from protocol receipt to approval), to measure program progress (e.g., approved protocols by department or by biosafety level), or to quickly find protocols by parameters such as cell lines or select agents used. Just as the approval process details vary among institutions, dashboard metrics will also vary.

There are two primary drawbacks with the use of SharePoint for research protocol management. First, SharePoint is an open application platform that is not designed specifically for protocol management. As a result, an institution wishing to develop its own SharePoint application independently would be required to spend significant time with the ultimate application developer to create an accurate scope of work prior to creating the application. Second, some institutions may find it difficult to design a SharePoint application that addresses every software requirement without significant outside consultation. For example, integration with other institutional systems (e.g., PeopleSoft, grant management software), while possible, can be complex (and thus costly) to implement.

Microsoft SharePoint offers a lower cost and flexible alternative to custom applications for managing the IBC protocol review process at many institutions. By taking advantage of a stable development platform already in place (or easily obtained), institutions can gain operational flexibility and also retain ultimate control of the application as well as associated costs. Institutions with in-house SharePoint expertise can develop an IBC application with a modest amount of effort. Most of that effort will be directed towards providing the developer with a detailed scope of the process to be modeled. Alternatively, EH&E BSOs have developed IBC applications on this platform in several large institutions and can provide a rapid initial development and roll-out of a customized application that can then be supported entirely by in-house expertise within the institution. For more information regarding the capabilities of SharePoint for IBC program management or EHS program management, feel free to contact me via e-mail at tmyatt@eheinc.com.

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