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Things to Consider When Implementing a New Electronic IRB Management System

Choosing the right electronic IRB management system for an organization is only the first of many steps. First and foremost, it is important to remember that communication is key throughout this process. Announcing and regularly updating stakeholders on upcoming changes and new expectations in advance will help to make the transition smoother. Considerations for a successful 'go-live' with an IRB e-system are as follows:

1. **System set-up and customization:** This process can vary greatly depending on the system. Activities typically include defining workflows and system settings and development of electronic forms, reviewer worksheets, and template documents (e.g., decision letters, reminder notices, agendas, minutes). Other considerations during this phase include:
    a. Ensuring the essential variables needed to facilitate reporting and searching are captured (for example, regulatory authority - NIH, FDA, Common Rule version, vulnerable populations, drug/device names, etc.).
    b. Determining IT requirements for integration with other systems (single sign-on, CITI, Conflict of Interest Management systems, etc.).
    c. Defining all user groups. For example, IRB staff, IRB members, researchers, and other users, as applicable (e.g., ancillary committee members, department Chairs responsible for electronic "sign-off", sponsored program office, etc.).

2. **Data conversion:** Organizations will need to decide what (if any) data related to existing studies will be imported into the new system and what data will remain in legacy records. For example, an organization may choose to import data on active studies only or on both active and closed studies. It is important to ensure that any data to be imported is correct.

3. **Testing the system:** Testing is very important to see if the system is working properly and allows for opportunity to address major issues prior to use. Testing may occur in several phases and should be conducted by different user groups. HRP recommends involving individuals from each user group in testing to get a good idea of things that may need to be fixed/changed prior to implementation. Organizations will still likely identify things to change after implementation, but thorough testing will help to troubleshoot and prevent the biggest issues.

4. **Documentation:** Prior to using the system, HRP recommends creating instruction manuals to 1) document the HRPP/IRB Office process expectations; and 2) serve as educational/training tools. Separate manuals should be created for each user group since each group will used the system differently.

5. **Training and Education:** Prior to using the system, HRP recommends providing education to each user group to help promote smooth implementation. This could consist of demos at an IRB/research personnel meeting, one-on-one training, etc. IRB members may require the most support while learning how to navigate the new system.