

**Institutional Review Board Q&A**  
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1. Confirming phone numbers: IRB-HSR and IRB-SBS (social behavioral sciences) are two separate branches of IRB, but in the long term, IRB wants to merge the two sides and make them more cohesive. The main IRB site is <https://hrpp.research.virginia.edu>. Users can navigate from there to **IRB-HSR** (<https://hrpp.research.virginia.edu/teams-irb-hsr>). Phone numbers are under the **Team Directory** (<https://hrpp.research.virginia.edu/leadership-and-staff>). The Team Directory has individuals listed for specific issues/concerns and their direct phone number.
2. Are there IRB office hours for students? Yes - go through [IRB-HSR Office Hours](https://hrpp.research.virginia.edu/about/contact-information/irb-hsr-contacts/irb-hsr-office-hours) (<https://hrpp.research.virginia.edu/about/contact-information/irb-hsr-contacts/irb-hsr-office-hours>), which is behind a NetBadge login.
3. Who are the pre-review IRB people? These are the analysts. Their role is making sure everything is consistent, making sure consent form is understandable and readable to participants. Researchers have to account for all education levels, as the average person has a 6-8th grade reading level. This is the biggest sticking point in pre-review.
4. Can we use DocuSign for electronic consenting? Yes, but we have to make sure it's Part 11 compliant. (The DocuSign used at UVA should be part 11 compliant. If you have questions, reach out to your IT department.) You will likely also be required to use MFA (multi-factor authentication) for remote/electronic consent.
5. Why do we have database-only IRB protocols if we cannot query them? If you want to collect data and keep it in a database or repository, your approval is to collect it. You can analyze it and do different things with it. If you want to send it outside of UVA or share it, IRB has to know about that.
  - a. Dr. Greene asked the following: Every time we make a database, we have to have an IRB to make it; then if we have to query it, we have to make another IRB. Is that correct? The response was no - you can include information in your initial IRB about querying that data. For existing databases, IRBs have to be modified to include querying; for new databases going forward, write queries into your IRB. If data will be shared outside of the UVA covered entity and that is not included in any IRB submission, the study will need to be modified to include that information, as well as a DUA obtained through Grants & Contracts.
6. What studies are exempt? Please visit <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html>. This website details categories of exemption. **Exempt means exempt from federal regulations, NOT exempt from IRB review.**

7. When something is expedited, it means that federal regulations apply but the study is minimal risk. [hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html](https://hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) Expedited doesn't go before the Board - it goes before one designated reviewer who can sign off on it.
8. Protocol Builder is your first stop when you're working on a new study - it generates templates (consent form, protocol, template). Then it goes into CR Connect, which helps walk you through the process, including triggering ancillary reviews.
  - a. On the other hand, IRB Pro is used at the end of the process. Upload all documents there - that's where you can get your most recent approved consent form, protocol. IRB Pro also has different modules for IRB meeting, including agendas and who the reviewers are. Once a study is approved, if you want to make changes, you do that through IRB Pro (submit modifications). Personnel changes can also be self-service through IRB Pro (as long as they've completed CITI training.) Once we move to HURON, however, everything will be in one system. Grants & Contracts and Conflicts of Interest already have HURON.
9. "The biggest hurdle is answering the questions in protocol builder." There's a lot of text to help you answer each of the questions, but it's almost too much information. Lots of information about the old programming language used to write Protocol Builder. Unfortunately, because Protocol Builder is an old system and there are limitations based on its original programming language, this is what we have to work with - but we're hoping to update it.
  - a. Is there a person you can work with for help? It depends on what kind of study you're building. Refer to the [Team Directory](#) for the most appropriate contact.