

# Institutional Review Board (IRB) Submission

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# What is the Institutional Review Board (IRB)?

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- A group regulated by the FDA to review and monitor biomedical research involving human subjects (1)
  - usually within a university or large organization
- Determine if the research project follows the ethical principles and federal regulations
- They have the authority to approve, require modifications in (to secure approval), or disapprove research
- Reviews research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.
- An IRB consists of at least five members of varying backgrounds:
  - a scientist member
  - a member whose primary concerns are nonscientific.
  - a member who is not affiliated with the institution (a community representative)



# Getting an IRB application started

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- The IRB application is a document the researcher submits to the IRB for review.
  - The document itself is often referred to as an IRB
- The IRB is a mandatory first step in any research project.
- Getting an IRB approval is the first step that makes a research project “official”
- As a student, resident, or post-graduate fellow, you are often the one tasked with completing the IRB
- An IRB application takes TIME. It is a lot of paperwork and isn't something you can put together overnight
- You are not allowed to start a study until the IRB approves it
- Over the years as a student, resident, and post-graduate fellow myself, I have seen the IRB as the greatest hurdle to getting a research project done.
- If you have a research idea, your first job is to get IRB approved as soon as possible!



# Required documents

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*\*Overall documents may vary depending on institution*

- IRB review form
  - provided by the institution that you are working in
- Proof of human subjects training (e.g. CITI, NIH, etc.)
  - anyone participating in research needs to complete an online course in research ethics and compliance
- Consent form
  - required for any prospective data collection involving human subjects. There are many types of consent (1) so make sure you have selected the correct one
- Recruitment materials (flyers, advertisements, etc.)
- Data collection instruments (e.g. SF-36, FFI, FAOS, etc.)
- Grant application if federally funded
- Signatures of approval—i.e. research chair, chief of department, department manager



# IRB areas to focus on

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- As the student, resident, or post-graduate fellow, the bulk of your work in the IRB is the study design itself. It essentially forms the backbone of your study when you submit it either as a poster or manuscript for publication
  - Study abstract
  - Study protocol—materials and methods
  - Research design
- Get help! (if available)
  - all academic institutions and most larger institutions have a designated staff of researchers (MPH, PhD, MS) who have experience with submitting an IRB and can help facilitate the majority of the application



# Sample questions from an IRB application

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1. What is the study objective? Primary and secondary outcomes?
2. Summarize the background and rationale for the study including a brief literature review
3. Why is this study important to the community?
4. What type of study is this? Retrospective or prospective?
5. How will you be obtaining written consent?
6. Is the study going to be funded? If so, what type?
7. How are the study subjects going to be recruited?
8. Is this study a clinical trial? If so it will need to be registered on [clinicaltrials.gov](https://clinicaltrials.gov)
9. How and where will you be obtaining the data?
10. What type of protected health information (PHI) will you be obtaining?
11. How will you be storing the data?
12. How will the participant's safety be monitored and assured?



## Example: *Comparing fusion rates between k-wire and intramedullary fixation in 2nd PIPJ fusion*

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1. Study objective/outcomes—fusion rates, complications, patient satisfaction, return to activity
2. Literature review on all methods of fixation for hammertoe
3. This study will help find the best implant for hammertoe correction
4. Prospective randomized? Observational study? Retrospective chart review?
5. Written consent handout? Who will be consenting the patients?
6. Are the implant industries funding the study?
7. Are the study subjects coming from multiple centers?
8. Is this study a clinical trial? Yes
9. Patient satisfaction surveys, AOFAS scoring system, independent radiologist reviewing fusion rates
10. Age, gender, comorbidities, date of surgery, post-operative radiographs, operative report
11. On the hospital's encrypted server?
12. Normal routine post-operative follow-up visits, serial radiographs



# Levels of IRB review

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## Full Board

- More than “minimal” risk to subjects
- Not covered under other review categories
- Example: interventions involving physical and emotional discomfort or sensitive data

## Expedited

- Not greater than minimal risk
- Fits one of the 9 Expedited Review Categories
- Example: collection of biospecimens by noninvasive means, Research with existing documents/record collected for non-research purposes in which subjects are identifiable

## Exempt

- Less than "minimal risk"
- Fits one of the 6 Expedited Review Categories
- Example: Research with de-identified records, anonymous surveys





# IRB approval timelines - Exempt

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- » A study can be **exempt** from IRB:
  - no more than “minimal risk” AND
  - in one of 6 exempt categories:
    1. Surveys
    2. Questionnaires or interviews
    3. Benign behavioral interventions
    4. Data used for research protected by HIPAA
    5. Research on teaching
    6. Research on instruction
- » Minimal risk—the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- » Exempt reviews are conducted by a member of IRB staff and do not require a full committee meeting



# IRB Approval Timelines - Expedited

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- » A study can be expedited
  - “minimal risk” AND the only involvement of human subjects will be one or more of the expedited categories
    - Collection of blood samples
    - Collection of biological specimen through non-invasive methods
    - Collection of data through non-invasive procedure (i.e. treadmill)
    - Research involving materials (data, documents, records, or specimens) that have already been collected
    - Collection of data from voice, video, digital, or image recordings made for research purposes
    - Research on individual or group characteristics or behavior or research employing survey or quality assurance methodologies
  - If it does not qualify as expedited it will be moved to full board review



# IRB Approval Timeline – Full Board

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- » A study requires **full board review** if it involves more than minimal risk and does not qualify for exempt or expedited review
- » Examples include:
  - invasive clinical procedures with drugs, devices, or biologics
  - new medical or surgical procedures
  - disclosure of information that could require mandatory legal reporting (e.g., child/elder abuse, etc.)
  - vulnerable populations (children, prisoner, pregnant women, and neonates)



# IRB availability

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- » Many hospitals and institutions have their own IRBs, if you are on staff, you may have ability to use them.
- » If you do not have a local IRB available there are fee for service IRBs:
  - Western IRB
  - Quorum Review



# Final thoughts

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- » The IRB is a tedious yet crucial step in the research process
- » Do not procrastinate!
  - Start the process early
  - It is not unusual for the IRB approval process to take several months from start to finish, as several revisions may be required and depending on the institution, the IRB may only meet at certain times of the month
  - Respond promptly to all emails, phone conference meetings, etc in the process and make revisions in a timely manner to avoid any delay in getting the IRB approved and for you to finally start the study
- » Ask for help if you need it
  - Especially if it is your first time completing one





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