10

Scientific Medical research

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Hello there, I hope you're doing ok. Anything highlighted in gray was added from the book to ensure coverage, I know it looks long, but the mere reading of the book additions is more than enough or you can choose to skip them altogether (tip from the mid exam: focus on the tables)

Also, I'd say watching the video makes it way easier to absorb.

23.1 Foundations of Research Ethics

The main laws of scientific medical research ethics evolved over time starting with

Nuremberg code (1947): mandated (فرض) voluntary consent (الموافقة الاختيارية) for experimental studies of humans

Declaration of Helsinki (1964): written by the world medical association to provide guidelines for physicians conducting clinical trials

Belmont report (1979): published for the protection of human subjects of biomedical and behavioral research to define key research principles and is a foundational document for the current U.S federal policy for protecting human research participants (often called: **the common rule**)

How were these laws born? Rights were violated, some people were denied the right to have the medication or got injected with a virus for the sake of research, and thus they immerged to protect the rights of participants. (more explanation below)

Book addition:

Experimental studies have traditionally raised the greatest ethical concerns because the researcher assigns participants to try a new product, take a new drug or supplement, adopt a new behavior, or otherwise engage in an activity they would not normally do.

Research ethics require that adequate, but not coercive benefits be offered to participants, an appropriate control must be selected, Safety must be monitored.

The ability of participants to continue to have access to the new product or service after the conclusion of the research project must be considered prior to the study implementation.

Observational studies have traditionally been considered less risky because the research team is not imposing changes on the participants.

However, observational studies usually still require informed consent from participants, and the researcher must still take care to maintain the confidentiality of all data and to minimize the physical, psychological, or other potential harms to participants.

23.2 Respect, Beneficence, & Justice

*These tables include questions the researcher should ask and answer about their protocol before ERC admission

There are three core principles of biomedical R ethics that each protocol of a primary research project should comply with:

1. **Respect for persons** is a broad concept that emphasizes **voluntariness** and **autonomy**.
   - The individual has the right to decide whether to volunteer in the study by their own free will
   - Each potential participant must be fully informed about the benefits and burdens of the study, the procedures involved, and the plans for use of the data collected.

2. **Beneficence** means that the study should do good
   - The research must have a high likelihood of benefiting individual participants and/or their communities
   - The opportunity to contribute to scientific knowledge is considered an adequate benefit to participants, although in some cases more specific individual and community benefits are offered.
   - **Nonmaleficence** means that the study should do no harm
   - Even if the results would be great, there shouldn't be any real harm in the process.
   - Nonmaleficence requires the research team to minimize potential physical, psychological, financial, social, or other harms to participants
   - Discontinuation of a study might be appropriate when the intervention appears to be dangerous or when it appears to be SO beneficial that it would be unethical not to immediately offer the intervention to the individuals assigned to the control group.
3. **Distributive justice** seeks to ensure that the benefits & burdens of research are equitable.
   - Even if there are unavoidable burdens, they shouldn't exceed the benefit.
   - To be just and not exploitative, the source population must have access to the results of the research study. For example: if an experimental therapy proves to be effective and safe, participants in the trial usually should have the continued opportunity to access the drug after the trial is over.
   - Justice is about the long-term impact of the study, and not just the immediate benefit.

FIGURE 23-2 Sample Ethical Considerations for Individual- and Community-Based Research Projects

	Individual Participants	Community Participants
Respect	• What steps have been taken to protect individual rights? • Has the risk of coercion in recruitment been considered and minimized? • Is the informed consent process more than just signing a piece of paper? • Do participants in sensitive studies have privacy? Will their participation be kept secret? • Will data shared with the researchers be kept confidential? Will it be locked in a protected place and not shared unless individually identifiable information is removed?	• What steps have been taken to ensure that a community's values are respected? • Are appropriate community-based research methods being used? • Have community representatives and a local oversight committee been consulted about the project?
Beneficence	• How will individuals benefit from participation? Free services, supplies, or medicines? Free health education? Gifts or money? Contribution to knowledge?	• How will a participating community benefit from the research project?
Nonmaleficence	• What steps have been taken to minimize physical, psychological, financial, social, and other risks to participants? • Is counseling available for participants in sensitive studies? • Is appropriate reimbursement for travel costs and other expenses being offered?	• What steps have been taken to ensure that a community is not burdened by research participation?
Justice	• What are the long-term benefits for individual participants? For example, will they gain increased knowledge about their health status? • What will happen to participants after the study is completed? Will the results of the study be shared with them?	• What are the long-term benefits of participation to the community? • Will the researchers have an ongoing relationship with the community?

Book addition:

Respect for persons also requires many other considerations, including:

- Choosing an appropriate source population for the research question or, if conducting community-based participatory research, selecting an appropriate research question for the source population
- Developing a scientifically valid and rigorous (careful) study protocol that will answer the research question
- Making research procedures as minimally invasive as possible
- Using a nondiscriminatory process to sample and recruit participants
- Recruiting the correct number of participants required to have adequate statistical power for the study
- Confirming that all participants understand the informed consent materials and process

FIGURE 23-1 Eight Central Considerations ("8 Cs") in Research Ethics

Category	Examples of Questions to Ask
Contribution	• Why is the proposed project important? • How will individuals and/or communities benefit from this study?
Compensation	• Will individuals or communities that participate in the study be offered any form of inducement, reimbursement, or compensation? If so, what will be offered, and is it appropriate? Is the offer so high that it could be seen as coercive or so low that the study could be seen as exploitative? • Are the risks of participation minimal? • How will study-related injuries be handled? • Are the risks and benefits balanced?
Consent	• How will potential participants be informed about the study? • How will consent to participate be documented? • Will a test of comprehension of the informed consent statement be required? • If applicable, how will consent (and possibly assent) be acquired for children and other members of potentially vulnerable populations? • If applicable, will community meetings be held prior to beginning the study?
Confidentiality	• How will the privacy and confidentiality of participants and their personal information be maintained?
Community	• Why is research in the selected population important? • Is the source population appropriate for the goals of the research study? • Will the selection process be fair? • Will the sample size be adequate? • Are potentially vulnerable participants adequately protected? • Has the protocol been adapted to address the cultural expectations of the source population? • If applicable, has the community agreed to participate in this project?
Conflicts of interest	• Who is contributing to the project's finances and/or logistics? • Might potential conflicts of interest inhibit the ability of a researcher to conduct ethical and unbiased research?
	analysis to ensure that the protocol and all ethical standards are adhered to by all members of the research team?
Committees	• Which research ethics committee(s) needs to review the project? • If applicable, what community organizations have been consulted about the proposed project?

8 Cs make up the central considerations of research ethics:

Contribution: a research should provide a benefit

Compensation: how a researcher pays back for the effort and time of participants

Consent: an informed consent

Community: what community will undergo your study and why not any other community? And the size should be adequate to provide statistical info but spare waste.

Conflicts of interest: The research results shouldn't be directly related to the publicity of the institution sponsoring it.

Collaborators: People working within the research.

Committees: This contributes to the reassurance that everyone's rights will be protected, by overview of the proposed means of execution by every committee concerned.

23.3 incentives and Coercion

There's a limit to the amount of reward (incentive) you give a participant, because over giving can turn into coercion.

Coercion is when you tempt someone by rewards to convince them of participating.

- Coercion (إكراه الناس على) is prohibited in any research concerning human subjects

The desire to thank the participant must be balanced with the need for the participation in any research project to be *voluntary.*

- It's not okay to give a participant a great amount of money for participation, because this indicates that the participants are in a great risk and you're basically tricking them into participation.
- To minimize the risk of coercion, researchers have to be very transparent about what participants will gain from participation in a research study and what they will not gain.

- Incentives that are given for compensation, like giving a participant a voucher to benefit from the institutes cafeteria is considered a mere 'thank you'
- In some situations, reimbursing participants for their travel and other expenses and/or compensating them for their time may be appropriate, KEEPING IN MIND that the incentive you're giving isn't creating a *coercion* for the participant to stay *involuntarily*.

- Coercion could include social pressure or requests from authority figures that make it difficult for an individual not to agree to enroll in a study
- To increase the participation rate, researchers may reasonably offer a small gift to everyone willing to participate.
- It may also be appropriate to provide free treatment for some types of conditions examined by the study, such as iron pills for participants found to have anemia after a blood test.
- For some clinical trials, covering all medical expenses directly related to participation in the study may be expected and appropriate. [pages 186-187 show more examples]

23.4 Informed Consent Statements (ICS):

Informed consent statements provide essential information about research projects to potential research participants so that they can make a thoughtful decision about whether to enroll in a study

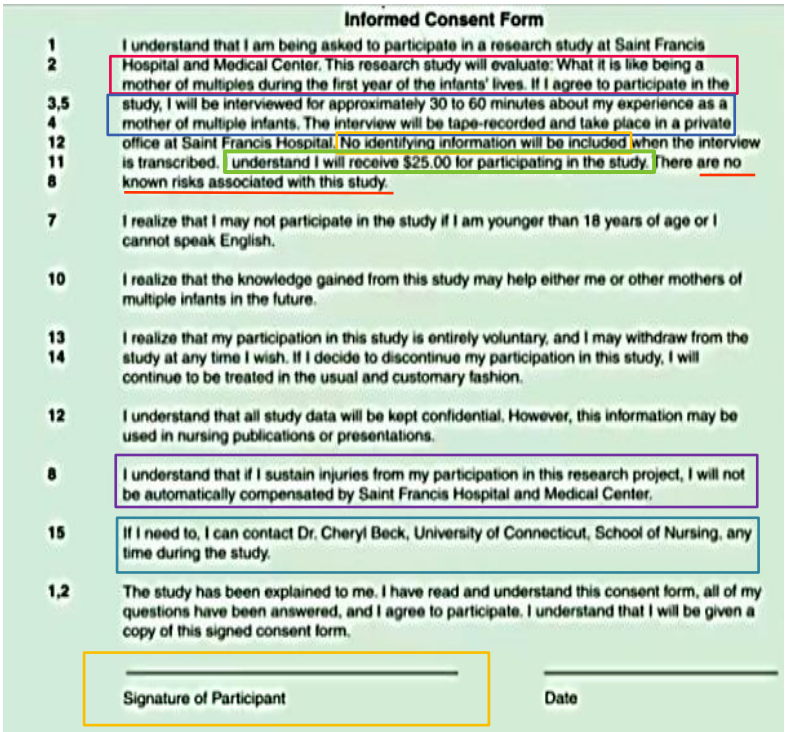
- **Informed consent means that the participant agrees to participate after fully understanding what the study is and how it's beneficial**
- The statement MUST use clear & simple language that the reader understands

This table shows the components of the ICS:

FIGURE 23-3 Content for the Informed Consent Statement

Content Area	Description
Research	A definition of "research" and a statement that the study involves research
Purpose	An explanation of the purpose and aims of the research process (except in the rare situations in which that interferes with the research goals)
Participants	A description of how and why certain individuals or communities were invited to participate in the research project and an estimate of the total number of individuals who will be recruited
Procedures	A description of the study procedures (including any physical exams, collection of biological specimens, randomization or blinding processes, interventions, or other procedures that are part of the study protocol) and the expected duration of the individual participant's involvement in the study
Benefits	A description of benefits to participants and/or to society, including a clear explanation of the compensation to be offered or a clear statement that the participant will receive no direct benefits
Risks	A description of the possible risks, discomforts, and costs associated with participation, a statement that involvement in the project may involve unforeseeable risks, and a description of how study-related injuries will be handled
Confidentiality	A description of the steps that will be taken to maintain confidentiality
Voluntariness	A statement that participation is voluntary and that the participant may withdraw from the study at any time with no penalty, along with a description for the process of withdrawing from the study
Contact information	Contact information for the researchers
Signature	Space for the participant's signature

- we have to enlighten the potential participant of the meaning of the word research itself, the purpose of the study, who are the participants and why they were chosen, procedures they'll undergo, what benefits will be gained and risks will be taken [risks should be very clear and very detailed to make sure the participant is fully willing to undergo the research]
- Reassure the participants of *confidentiality maintenance* by showing them the measures that'll be taken for their sake [تعهد]
- Make sure that the potential participant fully understands that **participation is a choice** not a must and that any participant *can withdraw from the study at any time* without penalty.
- lastly, contact information must be given for the participant to ask about anything they need, inform the researcher of abnormal effects, and inquire about results.



Informed Consent Form

I understand that I am being asked to participate in a research study at Saint Francis Hospital and Medical Center. This research study will evaluate: What it is like being a mother of multiples during the first year of the infants' lives. If I agree to participate in the study, I will be interviewed for approximately 30 to 60 minutes about my experience as a mother of multiple infants. The interview will be tape-recorded and take place in a private office at Saint Francis Hospital. No identifying information will be included when the interview is transcribed. I understand I will receive $25.00 for participating in the study. There are no known risks associated with this study.

I realize that I may not participate in the study if I am younger than 18 years of age or I cannot speak English.

I realize that the knowledge gained from this study may help either me or other mothers of multiple infants in the future.

I realize that my participation in this study is entirely voluntary, and I may withdraw from the study at any time I wish. If I decide to discontinue my participation in this study, I will continue to be treated in the usual and customary fashion.

I understand that all study data will be kept confidential. However, this information may be used in nursing publications or presentations.

I understand that if I sustain injuries from my participation in this research project, I will not be automatically compensated by Saint Francis Hospital and Medical Center.

If I need to, I can contact Dr. Cheryl Beck, University of Connecticut, School of Nursing, any time during the study.

The study has been explained to me. I have read and understand this consent form, all of my questions have been answered, and I agree to participate. I understand that I will be given a copy of this signed consent form.

Signature of Participant

Date

This is an example of an informed consent:

Study purpose: evaluate what it is like…

Procedure: I will be interviewed + tape recorded.

Confidentiality: No identifying info will be included.

Incentive: will receive 25$

Risks: non known

Contact info

No compensation

Signature

23.5 Informed Consent process

Informed consent is intended to be a process not merely a signed piece of paper,

- The goal of an informed consent is not to acquire signatures from potential participants, but to ensure that participants truly understand the research process.

Why process? Because all through the study and even afterwards we should have an ethical obligation towards the participants, to make sure they're well

- It's a process because it goes back and forth, until the participant is fully aware of everything, and agreeing to participate with full knowledge after all of their questions have been answered, 'The goal is not merely informed consent, but understood consent'.

The lines of communication between the researchers and participants must remain open during and even after the data collection process

- Examples: sometimes during the interview or even after the first interview, the participants feels insecure about participation and wants to withdraw, and in that case it's totally their right to do so, and it's our duty to reassure their complete comfort
- A copy of the consent with the contact information should be given to the participant

Book addition:

The informed consent process consists of the following steps:

- Reading the informed consent statement aloud to a potential participant or allowing the individual to read a copy of the statement
- Allowing adequate time for the potential participant to consider whether he or she wants to participate
- Answering any questions
- Asking whether the individual wants to participate in the study and is willing to sign an informed consent form

23.6 Informed consent documentation

For most research studies, the expectation is that each study participant **will sign** a **printed copy** of the informed consent statement and these are kept

- This written record provides legal protection for the institution sponsoring the research project because it shows that participants agreed to the terms of the study.

In a limited number of observational studies, the full process of acquiring and documenting individual informed consent may not be required because there's no direct interaction with the researcher or that no identifying info will be collected.

- Whenever the name of the participant is linked to the information collected an informed consent must be signed

Implied consent: these include studies where the participant will only be met once or no identifying information will be collected, the mere answering of questions or filling of the questionnaire is considered an implied consent.

- Sometimes it's written on the cover letter, that by filling this questionnaire you're agreeing to participate in this study.
- The consent should fit the situation: for illiterate people, a written consent is impropriate, alternatively oral consent is preferable in such situations.
- Any request not to require the full consent process must be approved by a REC.

Book addition:

Some anonymous questionnaires do not require an intensive informed consent process when:

- The responses cannot be linked to individuals.
- The survey instrument does not ask sensitive questions.
- The researchers will not physically examine Individuals or collect biological specimens.
- The questionnaire is so short that describing the study would take longer than completing the questionnaire form.
- There are no foreseeable risks to participants.

23.7 confidentiality and privacy

Privacy: is the assurance that the individuals **get to choose what information they reveal** about themselves (here we don't collect some info from the start)

The right to privacy means that:

- Individuals have the right to refuse to allow their personal infoto be shared with researchers.
- Individuals who agree to participate in a study involving face-to-face interviews should have the option of meeting with researchers in a place where no one outside the research team will be able to observe or overhear the interview.
- The identities of participants in a study should not be disclosed to unauthorized persons.

Confidentiality: is the **protection of personal information provided** to the researcher (here we may collect information but it's our duty to PROTECT them)

When Individually Identifying information must be collected, many steps can be taken to protect it.

- All paper records should be stored in a locked file box in a locked room, and all computerized data files should be password-protected.
- Names and other personal identifiers should not be included in data files that contain sensitive personal information. Instead, two separate files should be created, one for identifying Information and one for all other data. These should be linked only by a unique study identification number.
- Only essential research personnel should have access to the file containing personally identifying information.
- At some point after the end of the study, and in compliance with the rules of the relevant research ethics committees about how long documentation of informed consent must be stored. Individually identifying records should be destroyed.

23.8 Sensitive issues

Researchers asking questions about sensitive issues must decide ahead of time how to handle disclosures (e.g. disclosures of participation in illegal activities- like violence against women, drug abuse)

- ➲ We should plan ahead how we're going to acquire these information since they're sensitive, by giving incentives and pledging to confidentiality of the provided info.
  - ↳ Sensitive issues may include questions concerning:
    • Drug or alcohol abuse, Sexual practices and preferences, Psychiatric illnesses, immigration status, Participation in illegal activities, Genetic disorders

The researcher team can apply for a **certificate of confidentiality** that protects the identity of the participants from being subject to court orders & other legal demands for information

- ➲ Elaboration: normally after acquiring information about illegal acts, it's our duty to report them, however, a certificate of confidentiality means, you don't have a legal obligation to report any illegal acts you get informed of. This certificate is needed to convince people of those acts to participate in such studies.

23.9 cultural considerations

protocol is all the steps of research execution

A research protocol must be appropriate to the culture or cultures of the expected study participants (like assigning female data collectors to female participants, and same for males, and respecting preferences of the participants if you're visiting their homes for example)

- ↳ It may be helpful to have a **local advisory board** to facilitate communication between the community and the research team
- ↳ It is important to work with representatives of the source community when developing and revising the protocol. Additionally, some research ethics committees require a cultural expert to examine the protocol as part of the review process.

The informed consent process may also need to be adapted to local custom.

- ↳ Although Individual participants are always required to provide consent for their own participation, potential participants may need time to consult with their spouses. parents, or other family members prior to giving consent.

The survey instruments and data collection processes must also be culturally appropriate, and researchers must be trained in culturally respectful interview techniques.

There may be formal or informal restrictions on who can conduct an interview or a physical examination (women preferring females to examine them) more examples in pg 192

23.10 vulnerable populations

Some study populations are more exposed to risk than others, because they don't have the ability to fully understand the meaning of research and the extent of risks, and this may expose them to abuse and forcing them into participation.

Children and some adults with cognitive impairments may not be considered competent to make an informed decision (a condition for the integrity of an informed consent is the mental competency of the person singing it)

- Whenever possible, in addition to having **the legal representative's consent**, potential participants should assent (agree) to their own participation.

Other categories include: emotionally disabled, aged subjects, institutionalized people (imprisoned), poor people (either because of a low educational level or because of their economical status where incentives can create a persuading force to participate even if it wasn't large), adolescents, pregnant women, & unconscious or dying people.

- In addition to defending why a particular research project must focus on a potentially vulnerable population, extra care must be taken to ensure that the selection process is fair, potential participants understand that participation is voluntary, and participants (and/or their legal representatives) are fully informed about the possible benefits and risks of the study as well as about the requirements of participation.

23.11 Ethics training and certification

-Research ethics committees usually require everyone who will be in direct contact with research participants and/ or their personal data to complete formal research ethics training, so that the research worker will do their job knowing what considerations to make, and how to act. And all of this is to guarantee RCR.

Responsible Conduct of Research (RCR) training programs may also spell out expectations & procedures for disclosing conflicts of interest, avoiding research misconduct, and exhibiting professionalism as researchers.

- After completing modules on various aspects of research ethics and passing an exam, a certificate of completion is issued as evidence that the investigator has been appropriately trained in research ethics.
- Copies of these certificates should be saved because research ethics committees often require proof of ethics training for all members of the research team.

Chapter 24

24.1 Ethics committee Responsibilities

IRB: is a research ethics committee present in all institutions that host research involving people within the institution (like patients in hospitals, medical workers in hospitals, prisoners following the ministry of internal affairs, etc.)

The three primary goals of research ethics committees (RECs) often called **Institutional Review Boards (IRB)** are to:

1. protect the human subjects who will participate in research (along with the consent of the participant)
2. protect researchers by preventing them from engaging in activities that could cause harm (because they have the ability to turn down research proposals that seem inadequate)
3. legally protect the researcher's institution from the liability that could occur as a result of research activities (since it holds a lot of the responsibility).

The major functions of the ERBs are to:

1. review new and revised (an edited protocol by the recommendations of the board itself) research protocols
2. approve or disapprove of those protocols
3. ensure thar informed consent is documented (if required)
4. conduct continuing review of long-term research projects. (if a research is carried out over a long period of time, it has to be reapproved every year)

- To verify the achievement of these goals, IRBs maintain careful records of their procedures and membership; the decisions made and the justifications for these decisions. Researchers must provide all documents requested by the review committee.

24.2 Ethics committees composition

Research ethics committees are usually composed of **at least five members**, preferably from diverse backgrounds, including both scientist and nonscientists (من المجتمع المحلي).

- Each member reviews the proposal and then meets with the others to discuss it and to determine whether it meets the requirements of the institution.
- Because of the number of individuals involved in protocol review, even the most efficient ethics review committees may need a month or longer to decide. For complicated proposals, the review may take several months.
- A research timeline should assume a lengthy review period. The application should be submitted to the ethics committee as early as possible in the planning process

FIGURE 24-1 Examples of Information Requested and Examined by Ethics Review Committees

Category	Considerations
Participants	• What is the anticipated composition and size of the study population? • How will participants be recruited? Does the recruitment method raise any concerns about coercion? • What are the inclusion and exclusion criteria? Are they reasonable? • Is the source population appropriate for the study question? • Are potentially vulnerable subjects protected, if applicable?
Risks and benefits	• Why is the study important and necessary? How will the proposed study benefit participants and/or their communities? • How will data be collected? Will existing data, documents, records, or specimens be used? Will individuals or groups be examined using surveys, interviews, focus groups, oral histories, program evaluations, or other methods? Will interviews be audio or video recorded? Will noninvasive clinical measures be taken? Will participants be asked to engage in exercise or tests of endurance, strength, or flexibility? What machines will be used to collect data, and will collection involve radiation exposure? Will blood, hair, nail clippings, sweat, saliva, sputum, skin cells, or other biological specimens be collected noninvasively? Will drugs or devices be tested? • What are the potential physical, psychological, financial, or other risks to participants? • Are the risks minimal (or at least minimized)? • Are the risks reasonable compared to the anticipated benefits?
Informed consent	• Does the informed consent statement adhere to institutional guidelines? • How will informed consent be sought? • How will informed consent be documented? • Is any modification to the usual methods of documenting informed consent being requested? Is the request reasonable? (For example, are parents being asked to provide consent for their children, and are the children being asked to assent to participation? Or is a waiver of a signed consent form being requested because the source population has a low literacy rate? Or is a request being made to have no documentation of consent because the existence of a form linking an individual to the study could harm the participant?)
Privacy and confidentiality	• How will privacy and confidentiality be maintained? • What are the plans for the protection of computerized and noncomputerized data?
Safety monitoring	• Does the informed consent statement clearly state how research participants can contact the research team and/or the ethics review board if they have concerns? • What constitutes an adverse event? How will such events be handled?
Conflicts of interest	• How is the project being funded? • Do any financial or personal conflicts of interest need to be disclosed and/or addressed?
Researcher training	• Are the investigators prepared to conduct ethical research?
Documentation	• Are copies of all recruitment materials (if any) attached? • Are copies of the questionnaire and/or other assessment tools attached? • Is a copy of the informed consent statement attached? • Are copies of letters of approval from study sites and/or other ethics review committees attached, if applicable? • Is a copy of the grant proposal attached, if applicable? • Are copies of research ethics training certificates for all members of the research team attached?

24.3 Application Materials

when a person is presenting a research proposal to their institute, some IRBs require some materials along with it:

Some research ethics committees ask applicants to provide a narrative research statement that addresses a list of possible ethical concerns (a mere summary)

Others require the completion of dozens of pages of forms (a full proposal)

➲ The more risk there is, the more pages you're required to provide.

When you present a proposal to an IRB it's like you're answering a list of questions falling under multiple categories. (table)

Is the source population appropriate for the study question? Because we shouldn't be wasting people's time when we don't actually benefit from their participation.

Safety monitoring: how you'll maintain the safety of participants

Conflicts of interest: would the funding institution be confounding the results to fulfill a certain interest?

➲ The committee requires a copy of everything you're doing, to have a complete idea of what you're doing throughout this study.

Page 99 of the book contains things you should include in a proposal

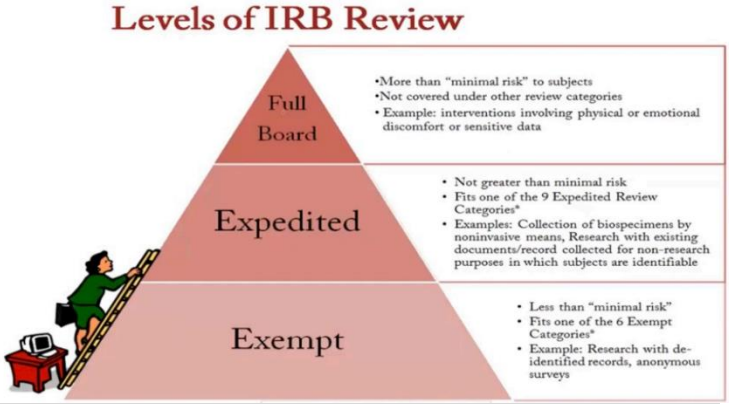
24.4 Review Process

Once all application materials have been submitted to a research ethics committee, there are three possible next steps:

Exemption (إعفاء)

Expedited review (مراجعة معجّلة)

Ful review (a long thorough review that may take months)



Most researches fall under exempt and expedited

Exemption (الإعفاء) from review is granted when even minimal risk doesn't exist especially where no identifying data are collected.

- Exemption from review is not allowed for research with classified vulnerable populations.
- Check the book page 200 to see situations where research is exempted

In expedited: There's a minimal risk, where there's collection of samples from participants or recording of names.

- may allow the chair of the ethics committee to approve the protocol without a full meeting of the committee

Full board reviews are spared to those researches that involve invasive procedures or sensitive data collection [even if the identities will be kept anonymous]

- Full review of the research proposal is usually required when an intervention will be tested in individuals or a community, data will be collected through interaction with individuals, Identifiable private Information will be collected, or other criteria for expedited review are not met. The ethics review board has the right to deny approval of any protocol that does not meet its standards.

24.5 Review By Multiple Committees

- Review by Multiple research ethics committees may be required to review studies that involve researchers from multiple institutions and/or participants from multiple countries or multiple study sites. Additionally, funding agencies may require review by their own ethics boards.

At least three issues must be resolved prior to submission of a research proposal to multiple committees:

- The application document that'll be required for each committee [commonly, each board will require its own unique application materials]
- The wording of the informed consent statement [The informed consent statement is seen as a legal document, and institutions want to be sure that the wording protects them]
- The order of review
  - The local institute of the researcher → the university to which he follows → the hospital he may be conducting the research in
  - Sometimes, all the committees Independently review the proposal at the same time. At other times, the reviews are conducted one after the other
  - If a modification of the protocol or informed consent document is mandated by one committee, then all other committees must re-review the proposal
- Getting a coded Signed and dated IRB approval is a necessity, because many journals would ask for a copy of this approval

24.6 Ongoing Review

All ongoing research protocols must be re-reviewed annually (or more often, at the discretion of the ethics review committee, depending on the potential risk of the research) until the completion of data collection or, In some cases, until the completion of data analysis

- Most committees require a final report to be submitted that at least states the number of participants, affirms that no adverse events occurred, and declares that the project is concluded.
- However, the research team may be asked to provide mid-year reports about the number of participants recruited in addition to immediately reporting all adverse events to the IRB.

Book addition:

The progress report (or re-review may need to include (depending on institutional requirements):

- Current versions of the protocol, informed consent statement, questionnaire, and other study documents
- A report on the study population, including the number of participants who have enrolled in the study and who have dropped out, the demographic characteristics of the study population, and basic information about the number of participants who are members of vulnerable populations
- A report of any adverse events, complaints, or unanticipated problems, including details about any issues reported to the ethics committee since the last annual review
- A list of any amendments to the protocol or study materials that are being requested
- A summary of findings (which are especially important for experimental studies that might need to be stopped early if the intervention appears to be harmful or very beneficial)

24.7 Conflicts Of Interest

- Most ethics review committees and an increasing number of journals require researchers to disclose potential conflicts of interest related to the study.

This is especially important when medical research is related to business, like pharmaceutical manufacture or any medical equipment industry in which the integrity of aiding and funding companies might be under observation

When a financial or other relationship (personal relationships, board membership, or others) could bias the design, conduct, or reporting of the study, **the potential conflict of interest (COI) must be disclosed** (معلنة)

The disclosure of a potential COI is not an admission of bias (because an honest researcher wouldn't do this, but it's just to say that being funded by a certain company presents a potential COI), but it is an important assurance of transparency.

As a researcher you have to answer the question of is there any potential COI? By including a disclosure statement in your reports.

For examples on relationships that pose a potential COI check book page 203

24.8 Is Ethics Review Required?

The short answer is YES

- Ethics review is required for almost every proposal that will involve living human subjects, whether those people will be directly contacted by the research team or their existing personal information will be analyzed.

A small subset of projects might be exempted from review but the decision to **exempt** a project from review can be made only by the relevant ethics committees.

Research protocols cannot be retroactively approved (ask for an approval after you collect the data and all), so researchers must take time to undergo a formal review prior to collecting any data or analyzing any data files.

Book addition:

Many incentives (حوافز) encourage participation in the formal review process:

1. Institutional approval provides a degree of legal protection to the researcher. An approval letter is evidence that the research plan was deemed reasonably safe by experts
2. Some granting agencies will not release funds until a research plan has been approved by a research ethics committee.
3. Finally, an increasing number of journals are requiring that authors provide details about which research ethics committee(s) reviewed the project (even if it was exempted from review). Some are even requiring copies of the official approval letters.