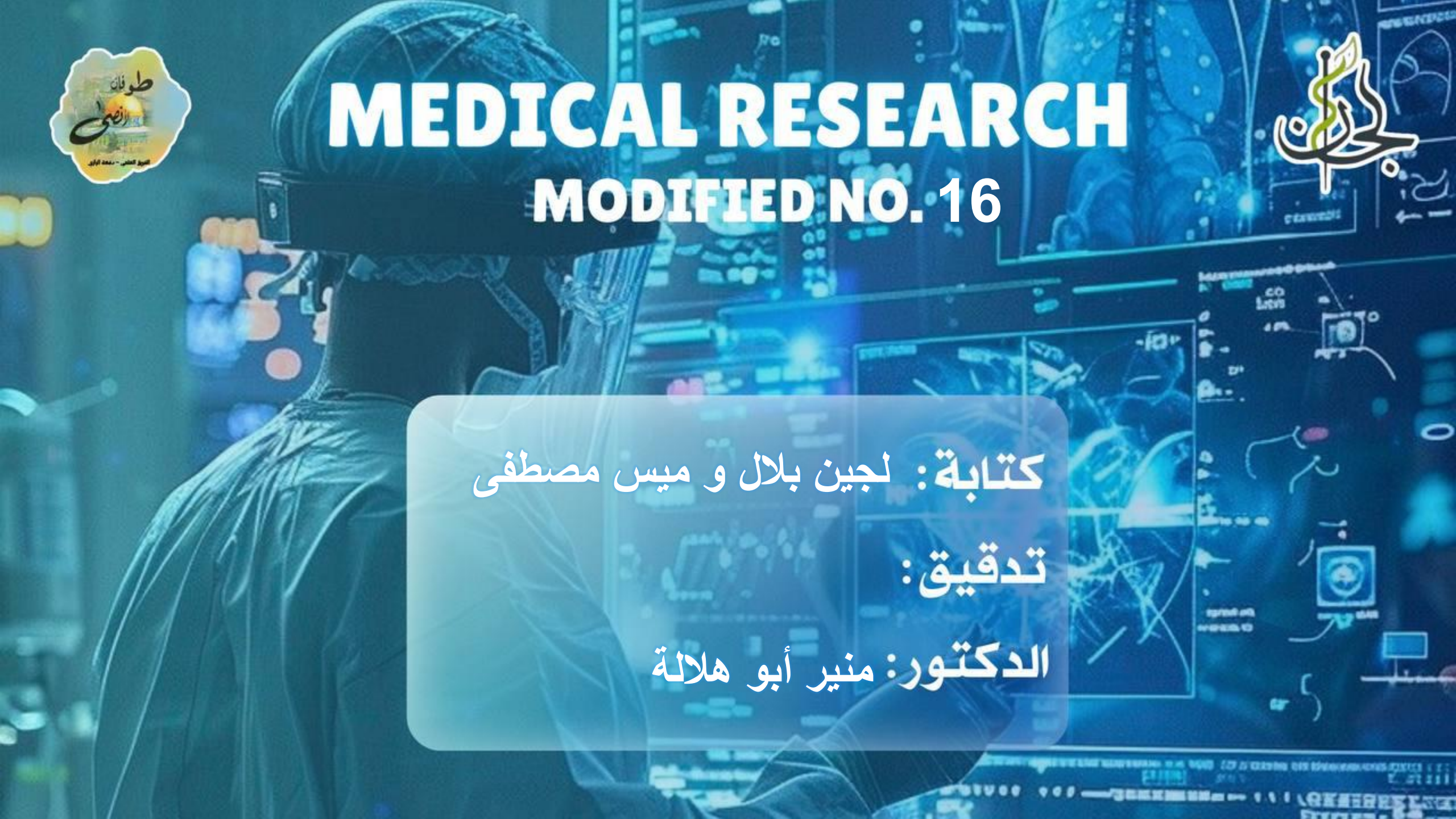

MEDICAL RESEARCH
MODIFIED NO.16
كتابة: لجين بلال و ميس مصطفى
تدقيق:
الدكتور: منير أبو هلالة

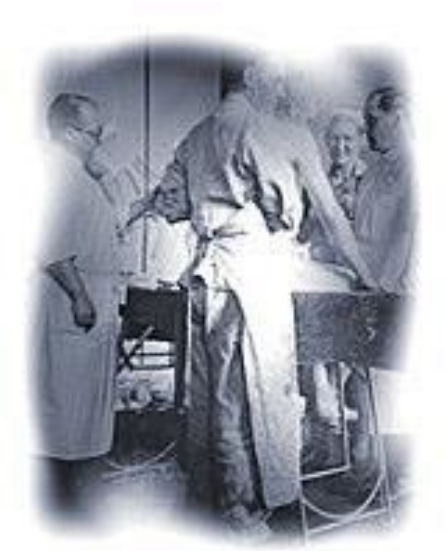
Color code

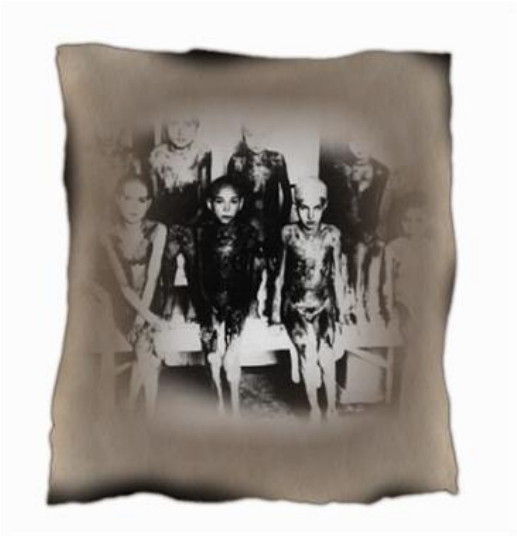
- Slides
- Doctor
- Additional info
- Important

Research Ethics and Good Clinical practice: Part 2

Welcome to the second part of the research ethics session. In this segment, we'll explore ethical principles, provide an overview of clinical practice, clinical trials, and clinical research, and discuss examples of writing consent forms. Additionally, we'll review the process of submitting applications to Ethics Committees to ensure everything is clear and practical.

Dr Munir Abu-Helalah
MD MPH PHD





After WW2, in October 1946, the *Nuremberg Medical Trial* began, lasting until August of 1947. Twenty-three German physicians and scientists were accused of performing cruel and lethal medical experiments on concentration camp inmates and other living humans between 1933 and 1945.

Fifteen defendants were found guilty, and eight were acquitted. Of the 15, seven were executed and eight were imprisoned.

1947 The Nuremberg Code

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

1947 The Nuremberg Code

- The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

- The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

1964 Declaration of Helsinki (Finland)

"In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject."

Why is Research Ethics Important?

- It is a reflection of respect for those who
  'take part' in research
- It ensures no unreasonable, unsafe or thoughtless demands are made by researchers
- It ensures sufficient knowledge is shared by all concerned
- It imposes a common standard in all the above respects

Why is Research Ethics Important

- It has become the norm as an expectation for research activity
- … a professional requirement for practitioners in some disciplines e.g. psychology
- … a requirement for access to participants in others e.g. health
- … and a requirement to comply with external REF's to obtain funding e.g. ESRC

•**REF** stands for **Research Excellence Framework**, which is a system used in the UK to assess the quality of research in higher education institutions.
•**ESRC** stands for **Economic and Social Research Council**, a major funding body for research in the social sciences in the UK.

The six key principles:

1. Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.

2. Research staff and participants must normally be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is allowed in very specific research contexts.

3. The confidentiality of information supplied by research participants and the anonymity of respondents must be respected.

The six key principles:

4. Research participants must take part voluntarily, free from any coercion.

5. Harm to research participants must be avoided in all instances.

6. The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

For example, when conducting clinical trials in collaboration with companies, it is important to clearly outline the methodology, proposal, protocol, and publication plans.

BPS Code of Human Research Ethics
By the British Psychological Society

- Respect for the Autonomy and Dignity of Persons
- Scientific Value
- Social Responsibility
- Maximising Benefit and Minimising Harm

BPS Code of Human Research Ethics

- Respect for the Autonomy and Dignity of Persons

Adherence to the concept of moral rights is an essential component of respect for the dignity of persons. Rights to privacy, self-determination, personal liberty and natural justice are of particular importance to psychologists, and they have a responsibility to protect and promote these rights in their research activities. As such, psychologists have a responsibility to develop and follow procedures for valid consent, confidentiality, anonymity, fair treatment and due process that are consistent with those rights.

BPS Code of Human Research Ethics

- Scientific Value

Research should be designed, reviewed and conducted in a way that ensures its quality, integrity and contribution to the development of knowledge and understanding. Research that is judged within a research community to be poorly designed or conducted wastes resources and devalues the contribution of the participants. At worst it can lead to misleading information being promulgated and can have the potential to cause harm.

BPS Code of Human Research Ethics

- Social Responsibility

The discipline of psychology, both as a science and a profession, exists within the context of human society. Accordingly, a shared collective duty for the welfare of human and non-human beings, both within the societies in which psychology researchers live and work, and beyond them, must be acknowledged by those conducting the research.

BPS Code of Human Research Ethics

- Maximising Benefit and Minimising Harm

… psychologists should consider all research from the standpoint of the research participants, with the aim of avoiding potential risks to psychological well-being, mental health, personal values, or dignity.

Research risks and harm, benefits and goods, and constituencies

Risks and harm

- Physical trauma/injury?
- Distress?
- Offence?
- Breach of confidentiality?
- Inconvenience?
- Coercion?
- Waste of time?
- Waste of resources /
- Funds?
- Disrepute or litigation?
- Failure to publish

Benefits and goods

We must ensure that research contributes to the development of theories and improvements in quality of life, highlighting the various benefits of clinical trials. While some pharmaceutical companies conduct research to develop new products and achieve commercial success, it is equally important that these efforts benefit human participants. Striking a balance between these aspects is essential.

- Research as intrinsic good?
- Contribution to knowledge?
- Development of theories?
- Improvements to lives?
- Training researchers?
- Career advancement?
- Enhancing reputation/image?
- Increasing commercial success?
- Entertainment and enjoyment?

Constituencies

- Participants
- Researchers
- Institutions
- Sponsors / funding bodies
- Society

Institutional Review Board (IRB)

- Also known as an Independent Ethics Committee (IEC) or Ethical Review Board (ERB) is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects .

Structure of Ethics Committees

1. Chair: Preferably from outside the Institution Having an external chair enhances impartiality and ensures that ethical reviews are free from institutional bias. However, if necessary, someone from the same institution may be appointed, provided they can maintain objectivity and independence.
2. Member secretary: from the same organization or institute
3. 1–2 Clinicians from various specialties
4. 1–2 Basic Medical Scientists
5. One legal expert or retired judge
6. One social scientist or representative of voluntary agency
7. One philosopher/ethicist
8. One lay person
9. According to the application, subject experts could be invited to offer views

A **lay person** refers to an individual who is not a professional or expert in the field of research, medicine, or the subject matter being reviewed by the Ethics Committee. They typically represent the perspective of the general public and contribute by ensuring that the research is understandable, ethical, and considers the interests and rights of participants. Their role is to provide an unbiased, non-specialist viewpoint to balance the expertise of other committee members.

- According to the application, subject experts could be invited to offer views

For instance, if we are conducting a study on leukemia, it is essential to involve an expert in the field. Their insights are crucial for evaluating the medications, inclusion criteria, and protocol to ensure the study is scientifically valid and feasible.

- The IRB must have at least five members.
- The members must have enough experience, expertise, and diversity (in reviewing medical research from an ethical point of view)
- If the IRB works with studies that include vulnerable populations, the IRB should have members who are familiar with these groups.

There is a difference between the scientific committee and the IRB committee. The scientific committee focuses on ensuring that the study's methodology is appropriate for achieving its objectives. In contrast, the Institutional Review Board (IRB) primarily aims to protect the rights and welfare of human subjects involved in the research.

- The IRB should include both men and women.
- The members of the IRB must not be all of the same profession.
- The IRB must include at least one scientist and at least one non-scientist. These terms are not defined in the regulations.

- The IRB must include at least one person who is not affiliated with the institution or in the immediate family of a person affiliated with the institution. These are commonly called "Community Members".
- IRB members may not vote on their own projects.
- The IRB may include consultants in their discussions to meet requirements for expertise or diversity, but only actual IRB members may vote.

Responsibilities of IRB

- Risks to study participants are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of study participants is equitable
- Informed consent is obtained and appropriately documented for each participant (We must ensure the consent form includes all essential information, such as the study objectives and a clear explanation of what participants will be exposed to during their involvement in the study.)

- Adequate provisions for monitoring data collection to ensure safety of the study participants
- Participant privacy and confidentiality is protected

The IRB/IEC should obtain the following documents

- Trial protocol(s)/amendment(s),
- Written informed consent form(s)
- Consent form updates that the investigator proposes for use in the trial
- subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB),

As investigators, we should not proceed with any amendments or changes to the trial without first obtaining approval from the IRB committee. The committee must also review and approve any modifications to the consent form. Additionally, the IRB should evaluate any recruitment processes, including advertisements. For example, in some countries, recruitment may involve advertising through social media, newspapers, or medical departments. Any relevant documentation to support the recruitment process must be provided to the IRB for review.

- **Information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications,**

You should also review the CVs of the investigators and their qualifications. For example, an investigator without a valid Good Clinical Practice (GCP) certificate should not be allowed to conduct the trial. Scientists without clinical experience or those who are not MDs cannot oversee clinical trials involving patients. All of these points must be considered in accordance with local regulations, as each country has its own set of rules. The IRB committee's role is to ensure that clinical trials adhere to both the site-specific requirements and the national guidelines and regulations.

- Available safety information,
- Information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications,
- Any other documents that the IRB/IEC may need to fulfill its responsibilities.

What Projects Need Ethical Approval?

- Human participants
- Use of the ‘products’ of human participants
- Animal participants
- Work that potentially impacts on human participants

- Where ethical approval is deemed unnecessary a disclaimer may be signed by researcher (and supervisor)

Key Ethical Issues

- Informed Consent – special consideration for minors
- Deception
- Need for debriefing
- Right to withdraw
- Confidentiality
- Safety and risk

What Else Does the Panel Need to Know?

- Summary of background to and rationale/justification for the proposal /protocol
- Nature of data to be collected
- Procedures and measuring tools/equipment (They should examine the interview questionnaire, chart review forms, and all related documentation. Additionally, they need to discuss the inclusion and exclusion criteria for participants, ensuring proper randomization.)
- Who are the participants?
- Where will data collection occur?
- How will data be stored and for how long? The data should be stored in a secure location, such as a locked cabinet, and we must ensure the confidentiality of the collected data. It is important to establish clear policies on what will happen to the data, information, and paperwork collected during the study over time—whether in two, three, or five years. These procedures should be outlined in the study's policies.

Full Procedure

- Complete Full Approval form
- Attach consent form, information sheet and additional material e.g. questionnaires

An information sheet is a document that provides a description of the study in language that is easy for a layperson to understand. While healthcare professionals can comprehend terms like "hypothyroidism," we should use simpler words and explanations that participants can easily grasp.

- Students must get form checked & signed by supervisor
- Submit to appropriate Ethics Panel – where Sub-Panels exist, staff and PG researchers must still submit to Faculty Panel
- DATA COLLECTION MUST NOT START UNTIL PANEL INFORMS

Outcomes of First Application

- Approved – must begin within the timescale indicated
- Approved subject to amendments –supervisor confirms with Chair of FEP
- Deferred
- Not Approved – major revisions and resubmit

Amendments can be either minor or major. Minor amendments can be modified and implemented to start the trial. However, for major amendments, you should not begin the clinical trial or research without resubmitting these changes to the IRB committee and waiting for their feedback.

Additional Issues

- Changes to original proposal must be notified
- Completion of project must be notified
- Adverse events must be notified
- Some applications will require evidence of risk assessment
- Some applications will require evidence of Police Clearance

What Is GCP?

Good Clinical Practice (GCP) is defined as a

‘standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are rotected’

The doctor emphasized the importance of becoming familiar with Good Clinical Practice (GCP). He encourages us to research GCP online and obtain the certification, ensuring it is renewed every two years, so that we will be eligible to conduct clinical trials after completing our medical degree and obtaining a medical license. GCP is a process that oversees the execution of clinical trials, ensuring proper design, conduct, performance monitoring, auditing, recording, and analysis. The IRB committee will review these aspects, grant approval, and receive reports on adverse drug reactions and study progress. The entire process of monitoring a study is referred to as Good Clinical Practice.

Good Clinical Practice Guidelines

- Are mainly focused on the protection of human rights in clinical trials.
- Provide assurance of the safety of the newly developed compounds.
- Provide standards on how clinical trials should be conducted.
- Define the roles and responsibilities of clinical sponsors, clinical research investigators, Clinical Research Associates, and monitors.

Good Clinical Practice Guidelines

- GCPs are generally accepted, international best practices for conducting clinical trials and device studies
  - They are defined as an international ethical and scientific standard for designing, conducting, recording and reporting trials that involve the participation of human subjects
  - Compliance with GCPs **provide public assurance that the rights and safety of participants in human subject research are protected and that the data that arises from the study is credible**

Under GCP, the FDA Requires That People be Informed:

- The study involves research of an unproven drug, the purpose of the research
- How long the participant will be expected to participate in the study
- What will happen in the study
- Possible risks/benefits to the participant
- Participation is voluntary and that participants can quit the study at any time without penalty or loss of benefits to which they are otherwise entitled.

The Food and Drug Administration (FDA) includes various organizations such as the Jordan Food and Drug Administration (JFDA), the U.S. FDA, the European Medicines Agency (EMA), and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.

- JFDA: Jordan Food and Drug Administration
- FDA: Food and Drug Administration (U.S.)
- EMA: European Medicines Agency
- MHRA: Medicines and Healthcare products Regulatory Agency (UK)

The Core of the Consolidated GCP Guidance

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirements

2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks

Sometimes, we conduct a site initiation to ensure that the site is fully prepared and ready to begin the clinical trial.

The Core of the Consolidated GCP Guidance

3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society

4 The available non clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial

If you are conducting a phase three clinical trial, you need to review the outcomes of phase zero and phase two. Similarly, if you are conducting a phase two clinical trial, you should examine the outcomes of phase zero and phase one.

4 Clinical trials should be scientifically sound, and described in a clear, detailed protocol

The Core of the Consolidated GCP Guidance

6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion

7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist

Thirteen principles of GCP Guidance

8. Each individual involved in conducting a trial should be qualified by educatio training, and experience to perform his or her respective tasks

9. Freely given informed consent should be obtained from every subject prior to clinical trial participation

Thirteen principles of GCP Guidance

10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification

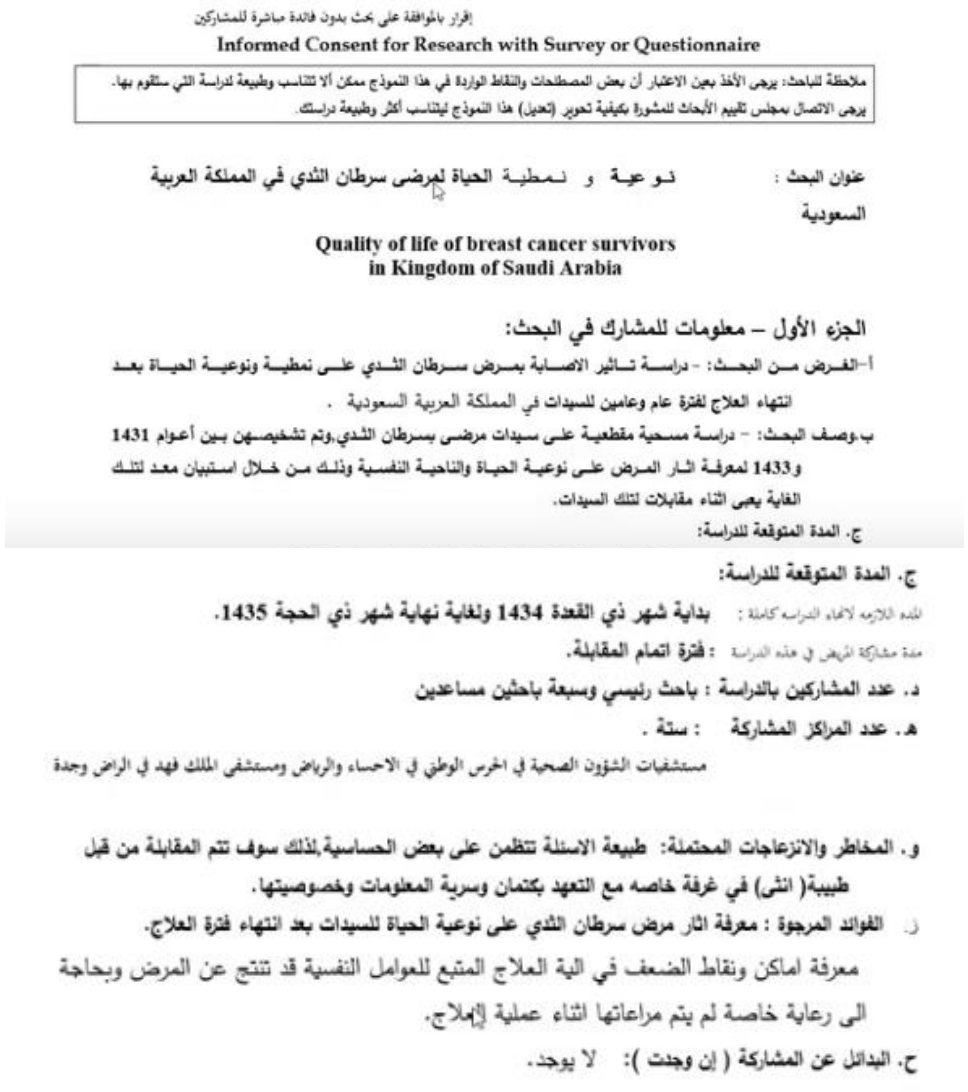
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements

Thirteen principles of GCP Guidance

12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol

13 Systems with procedures that assure the quality of every aspect of the trial should be implemented

The following slides show examples of consent forms presented by the doctor



إقرار بالموافقة على بحث بدون فائدة مباشرة للمشاركين

Informed Consent for Research with Survey or Questionnaire

ملاحظة للباحث: يرجى الأخذ بعين الاعتبار أن بعض المصطلحات والنقاط الواردة في هذا النموذج ممكن ألا تتناسب وطبيعة لدراسة التي ستقوم بها.
يرجى الاتصال بمجلس تقييم الأبحاث للمشورة بكيفية تحوير (تعديل) هذا النموذج ليتناسب أكثر وطبيعة دراستك.

عنوان البحث : نـو عيـة و نـمـطيـة الحياة لمرضى سرطان الثدي في المملكة العربية السعودية

Quality of life of breast cancer survivors in Kingdom of Saudi Arabia

الجزء الأول – معلومات للمشارك في البحث:

أ-الغـرض مـن البحـث: - دراسـة تـاثير الاصـابة بمـرض سـرطان الثـدي علـى نمطيـة ونوعيـة الحيـاة بعـد انتهاء العلاج لفترة عام وعامين للسيدات في المملكة العربية السعودية .

ب.وصف البحث: - دراسة مسحية مقطعية على سيدات مرضى بسرطان الثدي.وتم تشخيصهن بين أعوام 1431 و1433 لمعرفة اثار المرض على نوعية الحياة والناحية النفسية وذلك من خلال استبيان معد لتلك الغاية يعبى اثناء مقابلات لتلك السيدات.

ج. المدة المتوقعة للدراسة:

ج. المدة المتوقعة للدراسة:

المدة اللازمة لانهاء الدراسة كاملة : بداية شهر ذي القعدة 1434 ولغاية نهاية شهر ذي الحجة 1435.

مدة مشاركة المريض في هذه الدراسة : فترة اتمام المقابلة.

د. عدد المشاركين بالدراسة : باحث رئيسي وسبعة باحثين مساعدين

هـ. عدد المراكز المشاركة : ستة .

مستشفيات الشؤون الصحية في الحرس الوطني في الاحساء والرياض ومستشفى الملك فهد في الرياض وجدة

و. المخاطر والانزعاجات المحتملة: طبيعة الاسئلة تتظمن على بعض الحساسية,لذلك سوف تتم المقابلة من قبل طبيبة(انثى) في غرفة خاصه مع التعهد بكتمان وسرية المعلومات وخصوصيتها.

ز. الفوائد المرجوة : معرفة اثار مرض سرطان الثدي على نوعية الحياة للسيدات بعد انتهاء فترة العلاج.

معرفة اماكن ونقاط الضعف في الية العلاج المتبع للعوامل النفسية قد تنتج عن المرض وبحاجة الى رعاية خاصة لم يتم مراعاتها اثناء عملية الإعلاج.

ح. البدائل عن المشاركة (إن وجدت): لا يوجد.

This is the consent form for a study conducted on the quality of life of cancer survivors. It includes the study title, its purpose, the number of participants, details about the research team, as well as the potential risks and discomforts involved. Given the sensitive nature of some questions, the study was conducted in a private clinic.

We should outline the potential benefits of participation, clarify that there is no financial compensation, and emphasize that confidentiality will be maintained. Participation is entirely voluntary, and the form will include the name and contact information of the research assistant for any inquiries during the study.

https://research.ju.edu.jo/ar/arabic/FacultyForms/%D9%86%D9%85%D9%88%D8%B0%D8%AC%20%D8%A7%D9%84%D9%85%D9%88%D8%A7%D9%81%D9%82%D8%A9%20%D8%A7%D9%84%D9%85%D8%B3%D8%AA%D9%86%D9%8A%D8%B1%D8%A9.docx

This is another example, specifically the form required by the University of Jordan, which we need to follow. If students want to conduct research, they must complete this form. It should include the researcher's name, biographical information, phone number, and email, along with the study title, a description of the study, its aims and objectives, the steps involved, the duties of the research team, and what is expected from the study participants. It should also outline the duration of participation and describe any potential risks or benefits.

The form must explain how confidentiality and data security will be maintained and emphasize that participation is voluntary. If the study involves vulnerable populations, such as children, pregnant women, or individuals with certain illnesses who may not be able to make decisions independently, this should be clearly addressed.

Additional sections include the study duration, how adverse reactions (e.g., to drugs) will be monitored, and what will happen if harm occurs. The form should also describe how participants can access the results of the study, particularly if there are procedures like blood testing involved. For example, if blood tests are performed, the participants should be informed whether they will receive the results.

1. I understand that I will be participating in a study, which may, or may not benefit me directly, but will provide new knowledge, which could benefit other patients with similar conditions to mine in the future.

2. I also understand that I do have the right to withdraw from this study at any time, by telling my doctor. My decision to withdraw, or to decide not to participate, will in no way affect my ongoing treatment, to my relationship with my doctor.

3. I give permission for the doctor to read my medical records, and to publish or report the findings of this study at scientific meetings in the future, knowing that my identity will not be revealed. The doctor will explain the results of this study at the end.

1- أنا أعلم بأنني سوف أشارك في هذه الدراسة ومن المحتمل أن تكون ذات فائده بطريقة مباشره أو غير مباشره ولكنها سوف توفر معلومات يمكن أن تفيد مرضى آخرين بمثل حالتي في المستقبل.

2- بالإضافة إلى ذلك فإنني أعلم بأنه لي الحق في الانسحاب في أي وقت من هذه الدراسة وذلك بإخطار طبيبي المعالج بأنني قررت الانسحاب أو قررت عدم المشاركة ولن يؤثر ذلك على علاجي أو علاقتي بالطبيب

3- إنني قد فوضت الطبيب بمراجعة ملفي الطبي ونشر أو تقديم نتائج الدراسة في المؤتمرات العلمية في المستقبل مع عدم ذكر اسمي. وفي نهاية الدراسة سيشرح لي الطبيب نتائجها.

Signature			توقيع المريض
Witness			شاهد
Investigator/Doctor			الباحث / الطبيب

OPEN LETTER TO STUDY PARTICIPANTS

Interview with subjects who does not have currently hypothyroidism or hyperthyroidism

(No current history of subclinical, biochemical or over hypo- or hyperthyroidism)

TITLE
Prevalence of thyroid dysfunctional disorders in Jordan
PRINCIPAL INVESTIGATOR / DOCTOR
Dr Munir Abu-Helalah

عنوان الدراسة
اختلال افراز هرمون الغده الدرقية دراسة مسحية عن (مرض نقص هرمون الغدة الرقية ومرض زياده هرمون الغدة الرقية في الاردن
الطبيب الباحث
د. منير احمد عوض أبو هلاله

Having discussed this research project with

Dr.	

and reviewed the OPEN LETTER, which is attached, I agree, voluntarily to the participation in this study:

Patient's name	
Relationship	

بعد مناقشة بحث هذه الدراسة مع :

الطبيب	

ومراجعة المعلومات الملحقة عن الدراسة المرفقة فأنني أوافق طوعاً على المشاركة في هذه الدراسة .

اسم المريض	
العلاقة بالمريض	

دراسة مسحية عن
اختلال افراز هرمون الغده الدرقية
(مرض نقص هرمون الغدة الرقية ومرض زياده هرمون الغدة الرقية)

يقوم فريقنا البحثي الطبي بدارسة مسحية لمعرفة نسبة الاصابة بنقص او زيادة افراز هرمون الغدة الدرقية في الاردن ومعرفة مدى انتظام مستوى هرمون الغدة ونجاح العلاج للمرضى المصابين بأمراض زيادة او نقص الغدة الدرقية. حيث اننا نأمل بتحديد العوامل التي تزيد نسبة الاصابة بهذه الامراض في الاردن.

عزيزي - عزيزتي, مشاركتك في هذه الدراسة هي طوعية والفحوصات التي سوف يتم عملها لك هي مجانية.
علماً بأنه سوف يحافظ على سرية معلوماتك ونتائج الفحوصات خارج الفريق البحثي.

Here’s another example: This is a consent form for a cross-sectional study we conducted in Jordan, where we focused on the prevalence of hypo- and hyperthyroidism. The consent form is available in both Arabic and English.
It includes statements such as:
"I understand that by participating in this study, I may or may not directly benefit, but it will contribute new knowledge that could benefit patients with similar conditions in the future. I fully understand that I have the right to withdraw from the study at any time. My decision to withdraw or not participate will not affect my treatment or my relationship with my doctor.
I also give permission for my doctor to access my medical records and for the study findings to be published at scientific meetings, with the understanding that my identity will not be revealed.“

Sometimes, we include certain information either directly in the consent form or as a separate document known as the Patient Information Leaflet. In this document, we explain details about the study, including whether we will send the participants their results, such as whether their thyroid function is normal or abnormal. For some subjects who did not have medical insurance, we provided assistance for treatment after identifying them as subclinical hypothyroidism patients during our study.

In summary, we must always follow ethical research standards, ensuring the protection of human subjects and treating them with respect. We must also ensure that participants make their decision to take part or not without any undue influence, and that they can withdraw at any time without affecting the services they receive. We must reassure participants that their decision will not impact their care.
It's crucial to ensure the security and confidentiality of data and samples collected during the study. The study protocol must be carefully followed, and in clinical trials, for example, new medications must demonstrate the potential to improve or benefit the participants or future patients, balancing the benefits and risks.

It is illegal to start any medical research without approval from the IRB (Institutional Review Board) committee. They decide whether a study needs expedited or full review. We must prepare a consent form, and the IRB committee will determine if it's required. Once the study has begun, no amendments should be made without consulting the IRB, which will decide whether the changes are acceptable, including any changes to the consent form.
The goal of conducting research is to help patients, not harm them physically, mentally, or socially.
Note from Doctor: "I encourage you to pursue the GCB (Good Clinical Practice) certificate, as well as the NIH (National Institutes of Health) Medical Ethics certification. These certificates can be added to your CV and will help you conduct ethical research both in Jordan and internationally. I will provide the links for the courses on e-learning. These certifications can be renewed over time and will enhance your skills in conducting research according to ethical standards."

(رَبِّ هَبْ لِي حُكْمًا وَأَلْحِقْنِي بِالصَّالِحِينَ* وَاجْعَل لِّي لِسَانَ صِدْقٍ فِي الْآخِرِينَ* وَاجْعَلْنِي مِن وَرَثَةِ جَنَّةِ النَّعِيمِ)

VERSIONS	SLIDE #	BEFORE CORRECTION	AFTER CORRECTION
V1→ V2			
V2→V3			

امسح الرمز و شاركنا بأفكارك لتحسين أدائنا !!