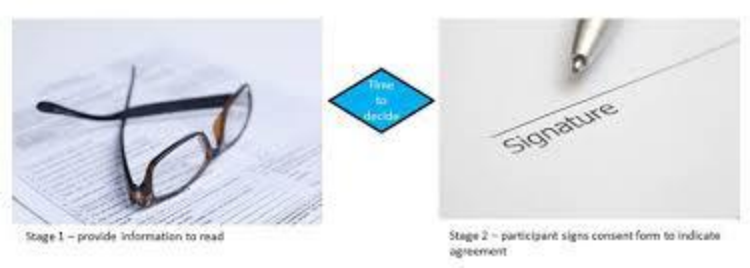

بسم الله الرحمن الرحیم

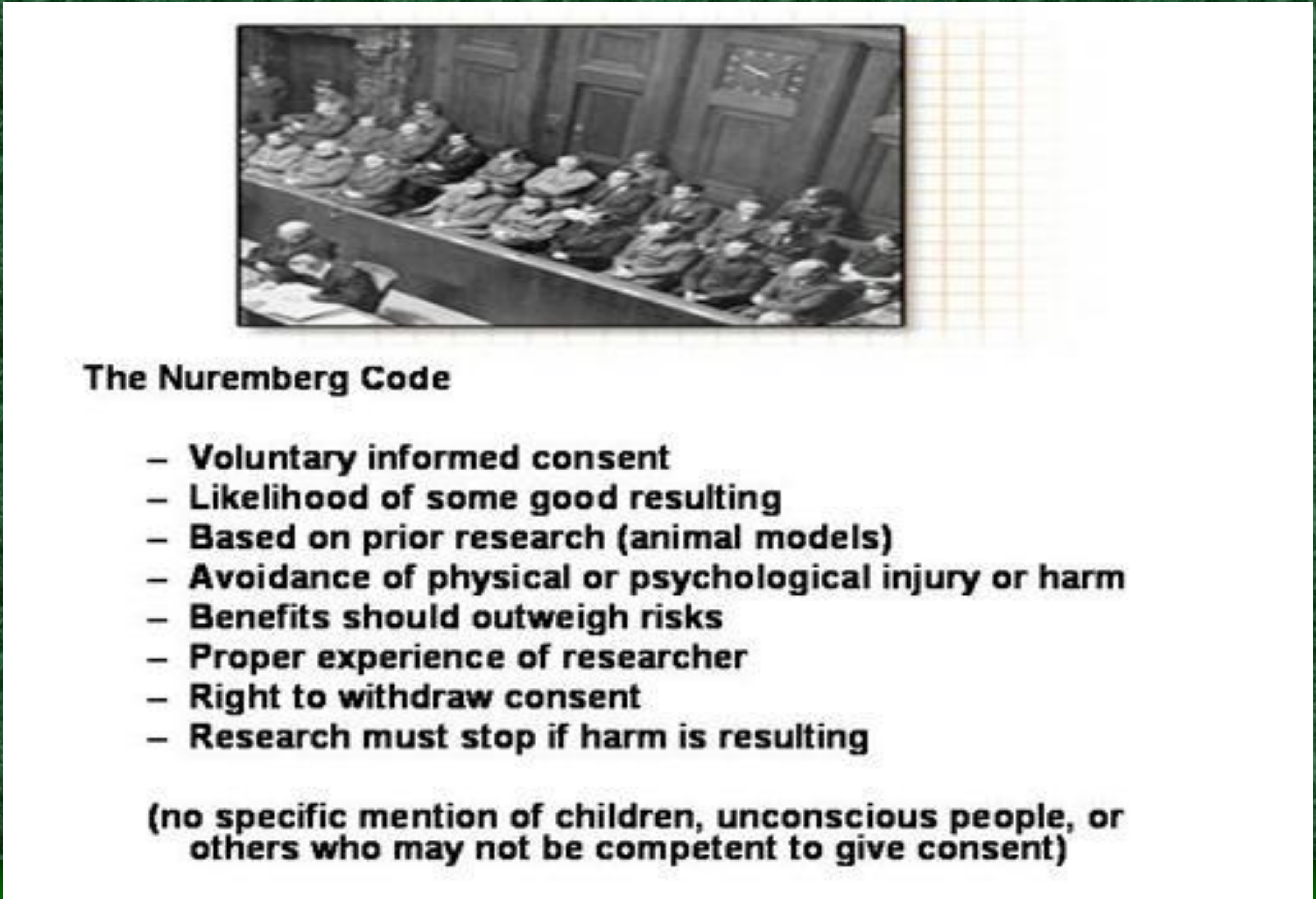
رضایت آگاهانه

در پژوهش



- What is an informed consent and why is it used in research?
- Why is it important to have an informed consent?
- What is a consent document?
- What is the informed consent form

The Nuremberg Code (1947)



The Nuremberg Code

- Voluntary informed consent
- Likelihood of some good resulting
- Based on prior research (animal models)
- Avoidance of physical or psychological injury or harm
- Benefits should outweigh risks
- Proper experience of researcher
- Right to withdraw consent
- Research must stop if harm is resulting

(no specific mention of children, unconscious people, or others who may not be competent to give consent)

Tuskegee Study

“Beginning in the 1930s, 399 men signed up with the *U.S. Public Health Service* for free medical care. The service was conducting a study on the effects of syphilis on the human body. The men were never told they had syphilis. They were told they had "bad blood" and were denied access to treatment, even for years after penicillin came into use in 1947. By the time the study was exposed in 1972, 28 men had died of syphilis, 100 others were dead of related complications, at least 40 wives had been infected and 19 children had contracted the disease at birth."

http://www.tuskegee.edu/global/Story.asp?s=1211670

The Belmont Report

- **Created in reaction to previous human subject violations** (e.g. Nuremberg Trials on human experimentation; Tuskegee Syphilis Experiment, etc.)

- **Named after the conference room** where the Commission convened at the *Smithsonian Institution's Belmont* Conference Center; held in 1976.

Respect for Persons

- Treat people as autonomous (having the right to self-govern) agents
- Protect those who have diminished autonomy (vulnerable populations), e.g. children, prisoners, elderly

Development of Helsinki Declaration

- the 18th WMA General Assembly, Helsinki, Finland, June **1964**,
- The 29th WMA General Assembly, Tokyo, Japan, October **1975**
- The 35th WMA General Assembly, Venice, Italy, October **1983**
- The 41st WMA General Assembly, Hong Kong, September **1989**
- The 48th WMA General Assembly, Somerset West, Republic of South Africa, October **1996**
- The 52nd WMA General Assembly, Edinburgh, Scotland, October **2000**
- Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington **2002**
- Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo **2004**
- Sixth revision, 59th Meeting, Seoul **2008**
- Seventh revision, Fortaleza, Brazil **2013**

Declaration of Helsinki

- 34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to *participate in a study or the patient's* decision to withdraw from the study must never interfere with the patient-physician relationship.

- Prnciples 22-29 in Declaration of Helsinki also relate to informed consent

اجزای رضایت آگاهانه

رضایت آگاهانه پنج جزء اصلی دارد:

- ❑اطلاعات
- ❑درک
- ❑تصمیم‌گیری آزادانه
- ❑ظرفیت تصمیم‌گیری
- ❑اختصاصی بودن

Numerous barriers to the informed consent process exist among patients, including

- impaired decisional capacity,
- impaired cognition,
- language barriers,
- illiteracy,
- insufficient time and communication
- vulnerable groups
- Clinical Equipoise

گروه های آسیب پذیر

کودکان

زندانیان

مهجورین

مبتلایان به آلزایمر

جنین

خانم های حامله

و ....

مساله تشابه بالینی یا
Equipoise (CE) Clinical

- CE is an attempt to answer the RCT dilemma
  - RCT is ethical ***only if*** the medical community is genuinely uncertain which of two treatment arms is superior
  - No subject randomized to a treatment known to be inferior

Therapeutic Misconception

- **Blurring the distinction between research and therapy (e.g., similarity position) risks undermining the entire process** of **informed consent**
- *Research subject's belief that enrolling in* research trial will (with certainty) provide direct therapeutic benefit, despite what appears to be an adequate informed consent process

Clinical Equipoise…

- CE promotes the therapeutic misconception at ***all levels*** (subject, investigator, IRB)
- The patient-subject who thinks he is getting individualized therapy when in fact he is being treated according to a research protocol cannot give informed consent

Therapeutic Misconception…

- 40-80% of subjects showed basic misunderstandings of research trial design
  - Appelbaum et al., *Hast Cen Rep* 17(2):20, 1987

- Have Things Improved?

"Our current research suggests that as many as 70% of subjects in a wide variety of clinical research studies may suffer from a *therapeutic misconception."*

  - Appelbaum, *AJOB* 2(2):22, 2002

Where Does the Misconception Originate?

- *Assumption: subject's psychological need* for an effective cure for her disease, despite honest effort at informed consent

- ***If*** investigator confuses clinical research with clinical therapy, stage is set for subject to get erroneous impression as to basic nature of the setting and activity

Conclusions

- Therapeutic misconception is a major practical problem in research
- Solid understanding of research ethics requires the clear distinction between research and therapeutic contexts (Difference Position)

Conclusions …

- به منظور ججلوگیری از این سوء برداشت باید کلینیسین ها، آزمودنی ها و نیز کمیته اخلاق در پژوهش متوجه باشند که همسانی و تشابه بالینی بین دارو یا روش مورد بررسی و روتین **صرفا** به معنی مساوی بودن از بعد منفی و نامَعلوم بودن برتری درمانی است نه از بعد مثبت و داشتن اثر درمانی

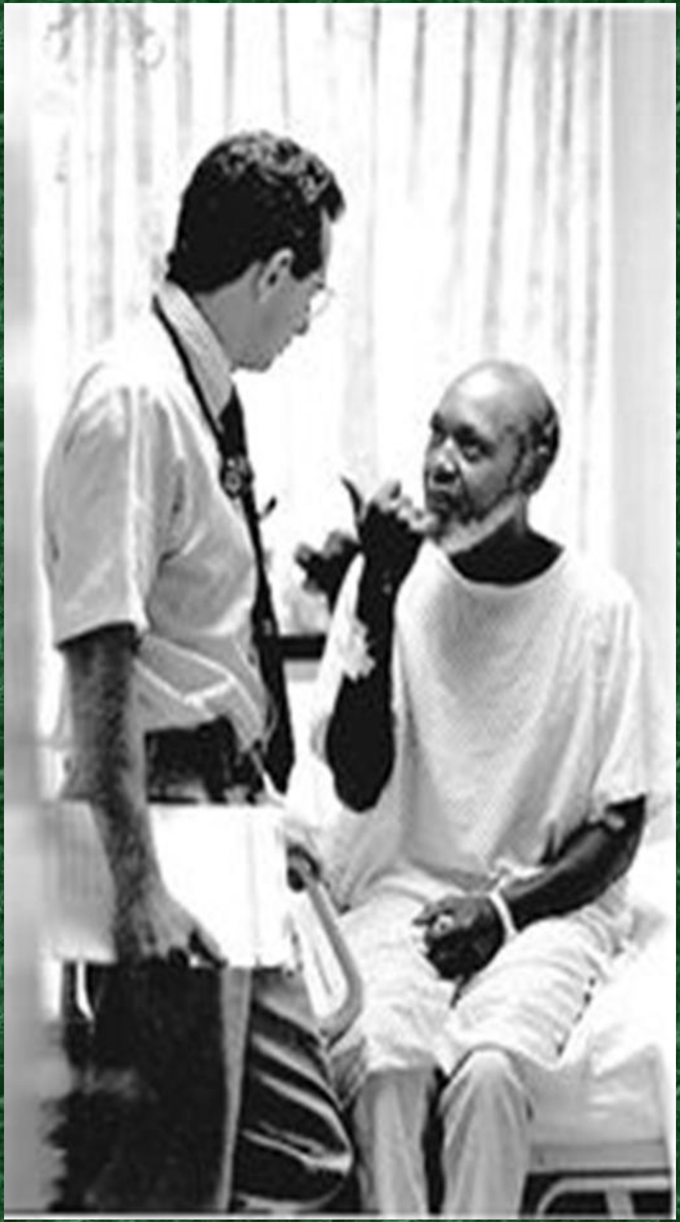
Is deception of subjects allowed when doing research?

- As a general rule, deception is not acceptable when doing research with humans. Using deception jeopardizes the integrity of the informed consent process and could harm participants, as well as eroding trust between the public and researchers.
- In some instances deception is necessary to conduct the research

Is deception…

- The IRB will carefully review any proposal that suggests using deception or misrepresentation. They will require an in-depth justification of why deception is necessary for the study and the steps that will be taken to safeguard participants, including a plan to debrief subjects at the end of the research.

We've run out of lab rats, Henderson... Put this on and come with us.



متدولوژی اخذ رضایت آگاهانه

رئوس نکاتی که در رضایت آگاهانه باید مد نظر قرَار گیرد

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. Procedures to be followed
4. Investigations to be performed
5. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
6. Benefits to participant, community or medical profession as may be applicable
7. Policy on compensation

8. Availability of medical treatment for such injuries or risk management

9. Voluntary participation

10. Steps taken for ensuring confidentiality

11. No loss of benefits on withdrawal

12. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

13. A copy of the participant/patient information sheet should be given to the participant for her/ his record.

راهنمای تهیه فرم رضایت آگاهانه در طرح های تحقیقاتی

برگ نخست

حاوی اطلاعات براي مشاركت كننده

تاریخ :

عنوان/موضوع تحقیق:

نوع تحقیق: [مداخله اي / غير مداخله اي / مصاحبه/ پرسشنامه /...]

آقاي / خانم محترم

از شما دعوت می شود در یک مطالعه تحقیقاتی که توسط [دانشگاه علوم پزشکی تبریز] انجام یافته و توسط [مثلاًسازمان بهداشت جهانی] تامین مالی می شود شرکت کنید. پیش از آنکه تصمیم به شرکت یا عدم شرکت بنمائید، من تحقیق را بطور خلاصه برای شما توضیح می دهم: چرا این تحقیق صورت می گیرد و این تحقیق مستلزم چه چیزی است. لطفاً در خواندن اطلاعات زیر در مورد تحقیق عجله نکنید و آنها را بدقت بخوانید. هر کجا نیاز به توضیح داشتید سوال فرمائید و در باره تصمیم در مورد شرکت یا عدم شرکت خودتان عجله نکنید.

ای تهیه فرم رضایت آگاهانه ....

هدف این مطالعه (تحقیق) چیست؟ و چگونه انجام خواهد شد؟ (هدف و روش) [حداکثر 120dکلمه]

- درdاینdبخشdبستهdبهdپژوهشdخودdبرایdشرکت کنندگانdبهdزبانd سادهdتوضیحdدهیدdکه:

- چهdمداخلهdایdبرdرویdآنهاdصورتdمیگیرد.
- dچهdاطلاعاتیdازdآنهاdمیپرسید
- چهdاقداماتdپاراکلینیکیdبرdرویdآنهاdانجامdمیشود.
- چهdنمونهdایdوdباdچهdحجمیdازdآنهاdمیگیرید
- dهمکاریdدرdاینdمطالعهdچهdمدتdطولdمیکشد.
- dدرdاینdمدتdچندdنوبتdمراجعهdبایدdداشتهdباشندdوdبهdچهdفواصلی
- هرdنوبتdمراجعهdچقدرdوقتdآنهاdراdمیگیرد
- درdفواصلdمراجعهdچهdاقداماتیdراdبایدdانجامdدهند
- dچهdاقداماتیdراdدرdپیگیریdآنهاdانجامdمیدهید.
- اگرdبطورdرندومdدرdیکیdازdگروههایdدرمانیdقرارdمیگیرندdاینdواقعیتd بهdآنهاdذکرdشود.
- اگرdهزینهdصرفdوقتdوdرفتdوdآمدdشرکتdکنندگانdراdجبرانdخواهید

منافع این تحقیق چیست؟ [حداکثر d70کلمه]

درdاینجاdمیتوانیدdسودdبالقوهdایdکهdشرکتdکنندگانdمیتوانندdاز
شرکتdدرdاینdپژوهشdببرندdبنویسید. اینdسودdمیتواندdشرحd
احتمالdدرمانdیاddتشخیصdبهترdبیماریشان،dدریافتdخدماتd
سلامتdرایگانdوdیاdپرداختdمشوقdمالیdدرdازایdجبرانd
همکاریشانdباشد. اگرdپژوهشdسودdمستقیمیdبَرایdشرکتd
کنندهdنداردdدقیقاdبهdآنdاشارهdکنیدdوdمی-توانیدdاینکهdشرکتd
آنهاdدرdپژوهشdمیتواندdبهdبهبودdروشهایdتشخیصیdوd
درمانیdبیمارانdآیندهdکمکdکندdراdذکرdکنید.

آیا خطر ویا عوارض احتمالي نیز در کار خواهد بود؟ (اگرdبلیd
چهdتضمینيdدادهdمیdشود؟) [حداکثر d70کلمه]

منظورdعوارضdوdمیزانdاحتمالdبروزdآنهاdدرdاینdمطالعهdاست.
لازمdاستddصادقانهdبهdعوارضdاحتمالیdاشارهdوdتاکیدdشودd
درdصورتdبروزdآنdهاdتیمdپژوهشیdدرdخدمتdشماdخواهدd

راهنمای تهیه فرم رضایت آگاهانه ....

آیا شرکت من در این مطالعه محرمانه خواهد ماند؟

شركت شما در اين مطالعه و اطلاعات / داده هايي كه شما در اختيار من مي گذاريد، كاملا" محرمانه باقي خواهد ماند. يك شماره و يا كد شناسايي در طول مطالعه براي هر يك از شركت كنندگان اختصاص يافته و تمام داده ها ناشناخته باقي خواهند ماند. در مورد داده ها مطابق با قوانين مراقبت از داده ها در ايران كه محرمانه بودن آنها را تضمين مي كند عمل خواهد شد.

اگر بخواهم شرکت کنم چه کاري باید انجام دهم؟

اگر شما براي شركت در اين مطالعه موافقت كنيد، لازم است فرم رضايت آگاهانه را تكميل نموده و به محقق برگردانيد. لطفا" اين برگ حاوي اطلاعات را براي خود نگهداريد. اگر تصميم به شركت در اين تحقيق گرفتيد، هر زمانی شمامجاز هستيد از اين تحقيق كناره گيري كنيد بدون اينكه دليلي براي ما اقامه نمائيد.

اگر شما سوالي داريد و يا اينكه مايل به اطلاعات

برگ دوم

رضایت آگاهانه

کد / شماره مطالعاتي:

عنوان تحقیق:

لطفاً علامت گذاری کنید:

۱- من تائید می کنم که برگ اطلاعات مشارکت کننده به تاریخ   را برای انجام تحقیق فوق خوانده و فهمیده ام و این فرصت برای من داده شده که سوالات مورد نظرم را بپرسم.

۲- من میدانم که شرکت من در این تحقیق داوطلبانه است. من همچنین می دانم که من هر زمانی که بخواهم می توانم از تحقیق کنار بکشم بدون اینکه ملزم به ارائه دلیل باشم.

۳- من موافقت می کنم که در مطالعه/ تحقیق فوق شرکت نمایم.

نام مشارکت کننده   تاریخ: امضاء

نام محقق   تاریخ: امضاء

رونوشت:

مشارکت کنند - محقق

http://researchvice.tbzmed.ac.ir/AFFAIRMAIN.htm

jeopardise

- put (someone or something) into a situation in which there is a danger of loss, harm, or failuree·rode
- **erode**; gradually destroy or be gradually destroyed

Belmont Report -Principles

• Respect for persons	Informed Consent
• Beneficence	Risks/Benefits
• Justice	Enrollment

تاریخچه برخی مسائل اخلاقی در تحقیقات

- مسائل اردوگاههای آلمانها در سال ۱۹۴۵ – ۱۹۴۳ (واکسن تیفوس و مرگ ۱۰۰۰ نفر)
- تزریق خون آلوده در مؤسسه روبرت کخ به ۴۰ نفر
- انتقال پشه‌های آنوفل از مردابها به اردوگاهها برای آزمایش بیماری مالاریا
- وارد کردن سنگ و شیشه به زخمها و جراحات ایجاد شده برای بررسی اثر سولفامید

تاریخچه برخی مسائل اخلاقی در تحقیقات

- مرگ بسیاری از دوقلوها برای بررسی اثرات ژنتيك
- تلاش آمریکاییها برای کشف واکسن شیگلا و استفاده از آن در افراد عقب افتاده
- مرگ ۷۰۰ نفر از ژاپنیها برای تلاش پژوهشگران ژاپنی در مورد بیماری طاعون
- بررسی تاسکجی ***(Tuskegee)*** بر روی سیاهپوستان در مورد سیر سیفلیس (مسئله فریب، نژادپرستانه بودن، عدم درمان با وجود درمان)

The Nuremberg Trials

Held for the purpose of bringing Nazi war criminals to justice, the Nuremberg trials were a series of 13 trials carried out in Nuremberg, Germany, between 1945 and 1949. The defendants, who included Nazi Party officials and high-ranking military officers along with German industrialists, lawyers and doctors, were indicted on such charges as crimes against peace and crimes against humanity. Nazi leader Adolf Hitler (1889-1945) committed suicide and was never brought to trial. Although the legal justifications for the trials and their procedural innovations were controversial at the time, the Nuremberg trials are now regarded as a milestone toward the establishment of a permanent international court, and an important precedent for dealing with later instances of genocide and other crimes against humanity.

The Road to the Nuremberg Trials

Shortly after Adolf Hitler came to power as chancellor of Germany in 1933, he and his Nazi government began implementing policies designed to persecute German-Jewish people and other perceived enemies of the Nazi state. Over the next decade, these policies grew increasingly repressive and violent and resulted, by the end of World War II (1939-45), in the systematic, state-sponsored murder of some 6 million European Jews (along with an estimated 4 million to 6 million non-Jews).

In December 1942, the Allied leaders of Great Britain, the United States and the Soviet Union "issued the first joint declaration

the defendants and prevent later accusations that the defendants had been condemned without evidence.

There were many legal and procedural difficulties to overcome in setting up the Nuremberg trials. First, there was no precedent for an international trial of war criminals. There were earlier instances of prosecution for war crimes, such as the execution of Confederate army officer Henry Wirz (1823-65) for his maltreatment of Union prisoners of war during the American Civil War (1861-65); and the courts-martial held by Turkey in 1919-20 to punish those responsible for the Armenian genocide of 1915-16. However, these were trials conducted according to the laws of a single nation rather than, as in the case of the Nuremberg trials, a group of four powers (France, Britain, the

توسعه اخلاق در پژوهش در ایران

- توجه ویژه به مقوله اخلاق در پزشکی از سال **۱۳۷۳**
- تشکیل **کمیته ملی تحقیقات در پزشکی** (۱۳۷۷)
- تشکیل کمیته‌های منطقه‌ای اخلاق در تحقیقات در دانشگاههای علوم پزشکی و مراکز تحقیقاتی (۱۳۷۸)
- تدوین **اصول ۲۶ گانه اخلاق درپژوهش** کشور (۱۳۷۹)

- *Informed consent protects the individual’s* freedom of choice and respect for *individual’s autonomy and is given* voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the **Informed Consent Form with Participant/ Patient Information Sheet**. The latter should have following components as may be applicable :

Clinical Equipoise-IV

- CE promotes the larger misconception that ***both*** physicians and research studies are nothing but retail pharmacies
  - Focuses solely on what treatment is received, not how the setting is designed or how treatment decisions are made

Consent - General Principles

- capacity

احراز صلاحیت و ظرفیت تصمیم گیری لازم فرد داوطلب برای اخذ رضایت

- voluntary

خودداری از هرگونه اجبار یا اعمال فشار بر شرکت کنندگان

- specific

تناسب رضایت اخذ شده با نوع تحقیق، فرایندها و پزشکان درگیر

- informed

افشاء حقایق و اطلاعات برحسب ضرورت

Clinical Equipoise…

- *“The Declaration of Geneva …binds the physician with the words, ‘The health of my patient will be my first consideration.’”*

- *“The primary purpose of medical research…is* to improve prophylactic, diagnostic and therapeutic procedures and the understanding *of the aetiology and pathogenesis of disease.”*
  - Declaration of Helsinki, WMA, 2000

- The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits. Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained

- *Informed consent protects the individual's* freedom of choice and respect for *individual's autonomy and is given* voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the **Informed Consent Form with Participant/ Patient Information Sheet**. The latter should have following components as may be applicable :

- راهنمای وزارتی در مورد رضایت آگاهانه