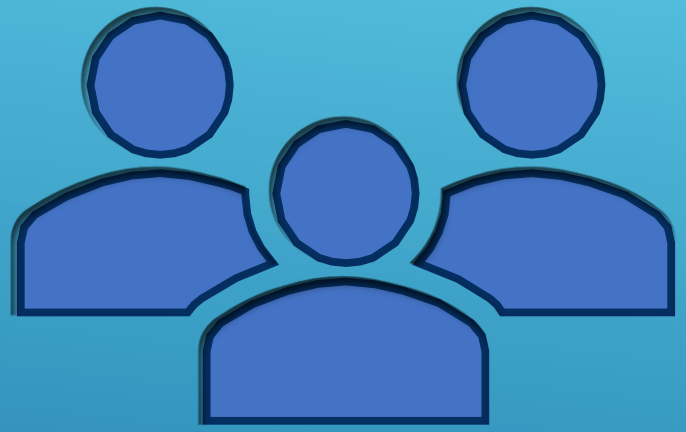
PATIENT RECRUITMENT

INFORMATION RELEVANT TO PARTICIPANTS AND QUESTIONS TO BE ASKED

RECRUITMENT DEFINITION



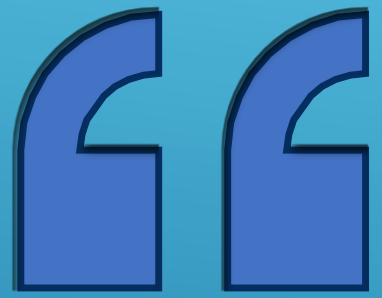
- SUBJECT RECRUITMENT involves an active effort to attract individuals within the pool of eligible subjects to participate in research.

- Aspects to take into account for SELECTION; RECRUITMENT AND RETENTION should be based on 6 principles:

1. Fair Distribution of burdens and benefits
2. Ensure social value of research
3. Enhance scientific validity
4. Minimize risk to subjects
5. Enhance benefits to subjects
6. Protect the Vulnerable

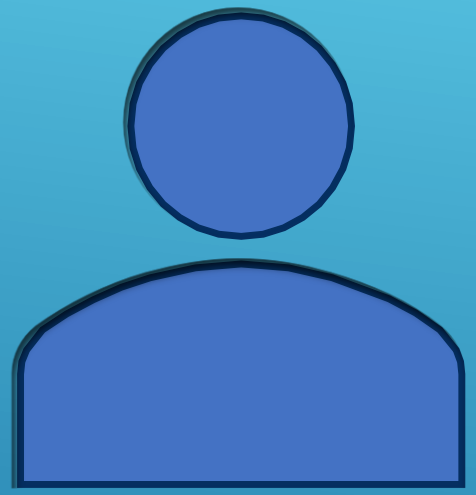
ASPECTS RESEARCHERS SHOULD TAKE INTO ACCOUNT BEFORE RECRUITING

INFORMATION RELEVANT TO PARTICIPANTS



- ANY INFORMATION PROVIDED TO PARTICIPANTS SHOULD BE GIVEN IN SIMPLE AND COMPREHENSIBLE TERMS AND WORDS.
- AS RESEARCHERS THREE BASIC PRINCIPLES ARE PARTICULARLY RELEVANT TO THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS:

1. RESPECT FOR PERSONS
2. BENEFICENCE
3. JUSTICE



- IMPLIES THAT INDIVIDUALS SHOULD BE TREATED AS AUTONOMOUS AGENTS AND SHOULD BE CONSIDERED CAPABLE OF DECIDING WHAT IS IN THEIR BEST INTEREST.
- IN ORDER FOR A PERSON TO TAKE AN INFORMED DECISION, RESEARCHERS SHOULD PROVIDE ALL REQUIRED INFORMATION THAT SUBJECTS MIGHT NEED.
- THIS INFORMATION SHOULD BE GIVEN IN SIMPLE WORDS.

RESPECT FOR PERSONS

RESPECT FOR PERSONS

- HOWEVER, NOT EVERY HUMAN BEING IS CAPABLE OF SELF DETERMINATION: YOUNG CHILDREN, MENTALLY DISABLED, CERTAIN TRANSIENT HEALTH CONDITIONS MAY AFFECT PATIENTS OR CIRCUMSTANCES THAT RESTRICT LIBERTY
- IN MOST CASES OF RESEARCH INVOLVING HUMAN SUBJECTS, RESPECT FOR PERSONS REQUIRE THAT THEY ENTER **VOLUNTARILY** AND WITH **ADEQUATE AND TOTAL INFORMATION ABOUT RESEARCH.**

- THIS INFORMATION RELEVANT TO PARTICIPANTS SHOULD BE INCLUDED AS PART OF A **PROCESS CALLED INFORMED CONSENT**.
- THIS PROCESS **STARTS WITH THE RECRUITMENT AND SCREENING** OF A SUBJECT AND THE SIGNING OF THE CONSENT DOCUMENT, CONTINUES THROUGHOUT THE SUBJECTS INVOLVEMENT IN THE RESEARCH AND EXTENDS BEYOND STUDY TERMINATION.

RESPECT FOR PERSONS

PROCESS OF INFORMED CONSENT

- INVOLVES DIFFERENT ASPECTS:
  - PROVIDING INFORMATION TO THE SUBJECT
  - ANSWERING QUESTIONS THE SUBJECT MAY HAVE TO IMPROVE HIS/HER COMPREHENSION OF THE STUDY
  - OBTAINING THE VOLUNTARY AGREEMENT OF THE SUBJECT TO PARTICIPATE IN THE STUDY.

ADVERTISING

- THE PROCESS OF INFORMED CONSENT IS CONCEPTUALIZED TO BEGIN AT THE RECRUITMENT STAGE.
- ADVERTISING CAN BE THE FIRST INFORMATION ABOUT RESEARCH SEEN BY SUBJECT AND IS MOST OFTEN USED IN RECRUITMENT.
- IT CANNOT BE COERCIVE OR MAKE FALSE PROMISES.
- ALL TYPES OF ADS (TV, MEDIA, FLIERS, E-MAIL MESSAGES, PHONE SCRIPTS…)SHOULD BE APPROVED BY AN IRB BEFORE THEY ARE USED.

INFORMATION CONTAINED IN ADS

- Should PROVIDE INFORMATION ON THE OBJECTIVES OF THE RESEARCH
- MUST NOT INCLUDE FALSE PROMISES OF A CURE.
- SHOULD INCLUDE THAT IT IS INVESTIGATIONAL
- SHOULD NOT BE UNDULY COERCIVE.
- PAYMENT SHOULD NOT BE EMPHASIZED OR THE AMOUNT OF INCENTIVVE TO RECEIVE

INFORMATION IN ADS

- THEY SHOULD **INCLUDE BENEFITS AND RISKS.**
- **CONFIDENTIALITY** should be included depending on the nature of the study and the pathology involved to avoid risk of stigmatization/losing jobs/ losing insurance.
- NAME AND WAYS TO CONTACT IF INTERESTED IN PARTICIPATE

- INFORMATION SHOULD BE COMMUNICATED IN A MANNER AND LANGUAGE THAT IS CLEAR AND UNDERSTANDABLE.
- TECHNICAL LANGUAGE SHOULD BE AVOIDED.
- INFORMATION SHOULD BE PROVIDED IN AN ORGANIZED MATTER, ALLOWING TIME FOR QUESTIONS AND ANSWERS.
- EXCULPATORY LANGUAGE SHOULD NOT BE EMPLOYED, EITHER IN THE DISCUSSIONS OR IN THE WRITTEN CONSENT

GUIDELINES FOR PROVIDING INFO

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- PROVIDE INFORMATION IN PERSONS NATIVE LANGUAGE IF UNABLE TO UNDERSTAND LANGUAGE OF THE AREA. USE A TRANSLATOR WHEN NECESSARY TO EXPLAIN THE INFORMED CONSENT AND TO PROVIDE ANSWERS TO SUBJECT`S QUESTIONS.
- THOSE WHO ARE NOT LITERATE SHOULD HAVE AN INTERPRETER OR WITNESS NOT BELONGING TO THE RESEARCH TEAM TO CERTIFY THAT THE INFORMED CONSENT WAS EXPLAINED TO PARTICIPANT AND THAT OPPORTUNITIES TO MAKE QUESTIONS AND RECEIVE ANSWERS WERE GIVEN.

- PROVIDE ENOUGH TIME FOR PERSON TO DECIDE WHETHER OR NOT HE/SHE IS WILLING TO PARTICIPATE.

GUIDELINES FOR PROVIDING INFO

RELEVANT INFORMATION TO PARTICIPANTS. GENERAL INFORMATION

- EXPLAIN THE GOALS AND OBJECTIVES OF THE STUDY AND WHY THE PERSON IS INVITED TO PARTICIPATE.
- MAKE EMPHASIS ON THE VOLUNTARINESS OF THE PARTICIPATION
- MENTION THAT HE/SHE CAN STOP THEIR PARTICIPATION IN THE STUDY AT ANY MOMENT AND HOW TO DO IT.
- NOT PARTICIPATING WILL HAVE NO IMPACT ON THE QUALITY OF HEALTH CARE IT WILL BE PROVIDED TO THEM, THERE WILL BE NO LOSS OF BENEFITS TO WHICH SUBJECTS ARE OTHERWISE ENTITLED.

- PROVIDE INFORMATION ON ALTERNATIVE TREATMENTS FOR PARTICIPANT´S CONDITION, IN CASE THE DECISION IS NOT TO PARTICIPATE IN RESEARCH.

RELEVANT INFORMATION. ALTERNATIVE TREATMENTS

INFORMATION TO PARTICIPANTS

- LENGTH OF THEIR PARTICIPATION. NUMBER OF PARTICIPANTS.
- PARTICIPANT DUTIES AND RIGHTS SHOULD ALSO BE ADDRESSED (#of visits, filling of forms, treatment compliance, etc.)
- EXPLAIN ALL THE PROCEDURES THAT ENCOMPASS THEIR PARTICIPATION AND RISKS OF SUCH PROCEDURES.
- IF PARTICIPANTS WILL BE RANDOMLY ASSIGNED TO ANY OF 2 GROUPS: CONTROL AND EXPERIMENTAL, THAT SHOULD BE CAREFULLY EXPLAINED.

INFORMATION RELEVANT TO PARTICIPANTS. RISKS

- DESCRIBE ANY FORESEEABLE DISCONFORTS AND RISKS TO THE SUBJECT OR TO OTHERS, SUCH AS THE FOETUS IN CASE A WOMAN GETS PREGNANT (IF THERE IS ANY).
- EXPLAIN CLEARLY THE RISKS OF PARTICIPATING, SO THAT THE PERSON COULD WEIGH RISKS VS BENEFITS OF PARTICIPATING.
- STATE WHAT ADVERSE EVENTS CAN OCCUR AND WHAT TO DO IN CASE OF OCCURRENCE: WHOM TO CONTACT; WHERE TO GO AND WHO WILL COVER MEDICAL COSTS.

- BENEFITS TO THE INDIVIDUAL SHOULD BE CLEARLY EXPLAINED. IF, THERE ARE NO INDIVIDUAL BENEFITS, THIS MUST BE STATED CLEARLY TOO.
- HOPE TO LEARN HOW GAINED KNOWLEDGE WILL CONTRIBUTE TO THE FIELD OF STUDY.
- STATE POSSIBLE BENEFITS FOR THE COMMUNITY OR OTHERS IN THE FUTURE.

BENEFITS: INDIVIDUAL VS COMMUNITY.

INFORMATION RELEVANT TO PARTICIPANTS. COSTS COVERED

BE SPECIFIC ON WHAT COSTS WILL NOT BE COVERED AND WHICH ARE COVERED AS PARTICIPANTS.

IF THERE IS A LIABILITY POLICY FOR LESIONS DUE TO THE TRIAL, THAT INFORMATION SHOULD ALSO BE PROVIDED TO PARTICIPANTS.

WHAT WILL HAPPEN AFTER THE END OF THE TRIAL.

INFORMATION RELEVANT TO PARTICIPANTS. INCENTIVES

- **INCENTIVES** ARE PAYMENTS OR GIFTS OFFERED TO SUBJECTS AS REIMBURSEMENT FOR THEIR PARTICIPATION.
- PARTICIPANTS SHOULD BE AWARE OF THE CONDITIONS UNDER WHICH THEY WILL RECEIVE PARTIAL OR NO PAYMENT.
- USUALLY INCENTIVES **SHOULD NOT** BE HIGH ENOUGH TO **EXERT A COERCIVE** OR **UNDUE INFLUENCE** IN THEIR DECISION TO PARTICIPATE IN THE STUDY.
- USUALLY INCENTIVES INCLUDE: TRANSPORTATION COSTS, FOOD, COMPENSATION FOR WORK HOURS LOST DURING VISITS

- PROVIDE INFORMATION DESCRIBING THE EXTENT, IF ANY, TO WHICH CONFIDENTIALITY OF RECORDS, DATA AND RESULTS IDENTIFYING THE SUBJECT WILL BE MAINTAINED.
- DESCRIPTION SHOULD INCLUDE A FULL DISCLOSURE OF ANY STATE-MANDATED REPORTING REQUIREMENTS, such as suspicion of child abuse and /or neglect , when warranted by the topic under investigation.

RELEVANT INFORMATION. CONFIDENTIALITY

DISCLOSURE OF RESULTS

- PROVIDE INFORMATION ON DISCLOSURE OF RESULTS TO PARTICIPANTS OR FAMILY MEMBERS.
- EXPLAIN WHICH RESULTS WILL NOT BE DISCLOSED.

ADDITIONAL ELEMENTS

- ANTICIPATED CIRCUMSTANCES UNDER WHICH THE SUBJECT`S PARTICIPATION MAY BE TERMINATED BY THE INVESTIGATOR WITHOUT REGARD TO THE SUBJECT`S CONSENT.
- BEST INTEREST ON THE SUBJECT
- SPONSORS DECISION
- PRELIMINARY STUDIES SHOW NO EFFECT OF THE TRIAL.

ADDITIONAL ELEMENTS

- ANY ADDITIONAL COSTS TO THE SUBJECT THAT MAY RESULT FROM PARTICIPATION IN THE RESEARCH
- CONSEQUENCES OF A SUBJECT`S DECISION TO WITHDRAW FROM THE RESEARCH AND PROCEDURES FOR ORDERLY TERMINATION OF PARTICIPATION BY THE SUBJECT.
- What happens to the data or samples collected if they withdraw midway through the study.
- How their compensation might be affected if they choose not to complete an interview

ADDITIONAL ELEMENTS

- INCLUDE A STATEMENT THAT SIGNIFICANT NEW FINDINGS DEVELOPED DURING THE COURSE OF THE RESEARCH WHICH MAY RELATE TO SUBJECTS WILLINGNESS TO CONTINUE PARTICIPATION WILL BE PROVIDED TO THE SUBJECT.

- AN ASSENT SHOULD BE OBTAINED FROM MINORS WHO ARE IN THE RANGE OF AGE THAT ALLOWS THEM TO ASSENT.
- INFORMATION PROVIDED TO CHILDREN AND ADOLESCENTS SHOULD BE GIVEN IN A LANGUAGE APPROPRIATE TO THEIR AGE LEVEL.
- EMPHASIZE VOLUNTARINESS OF THEIR PARTICIPATION AND THAT PARTICIPATION WILL NOT OCCUR IF THEY DO NOT WANT TO, EVEN IF THEIR PARENTS HAVE AUTHORIZED THEIR PARTICIPATION IN THE STUDY.

IN CASE OF MINORS TAKING PART IN RESEARCH STUDIES

- PROVIDE CONTACT INFORMATION OF PI IN CASE ADDITIONAL QUESTIONS ON THE STUDY ARE REQUIRED.
- PROVIDE AN EXPLANATION OF WHOM TO CONTACT FOR INQUIRIES CONCERNING RESEARCH SUBJECTS`RIGHTS AND
- WHOM TO CONTACT IN THE EVENT OF A RESEARCH-RELATED INJURY TO THE SUBJECT.

INFORMATION RELEVANT TO PARTICIPANTS. ADDITIONAL QUESTIONS

1. INFORMATION PROVIDED TO PARTICIPANTS MUST BE GIVEN IN SIMPLE TERMS AND IN THEIR OWN LANGUAGE.
2. MUST BE AS COMPLETE AS POSSIBLE.
3. OPPORTUNITY FOR ASKING QUESTIONS SHOULD BE GIVEN.
4. ENOUGH TIME SHOULD BE PROVIDED TO ALLOW FOR AN INFORMED AND WELL MEDITATED DECISION TO PARTICIPATE.

SUMMARY