Understanding Clinical Trial Recruitment Rules

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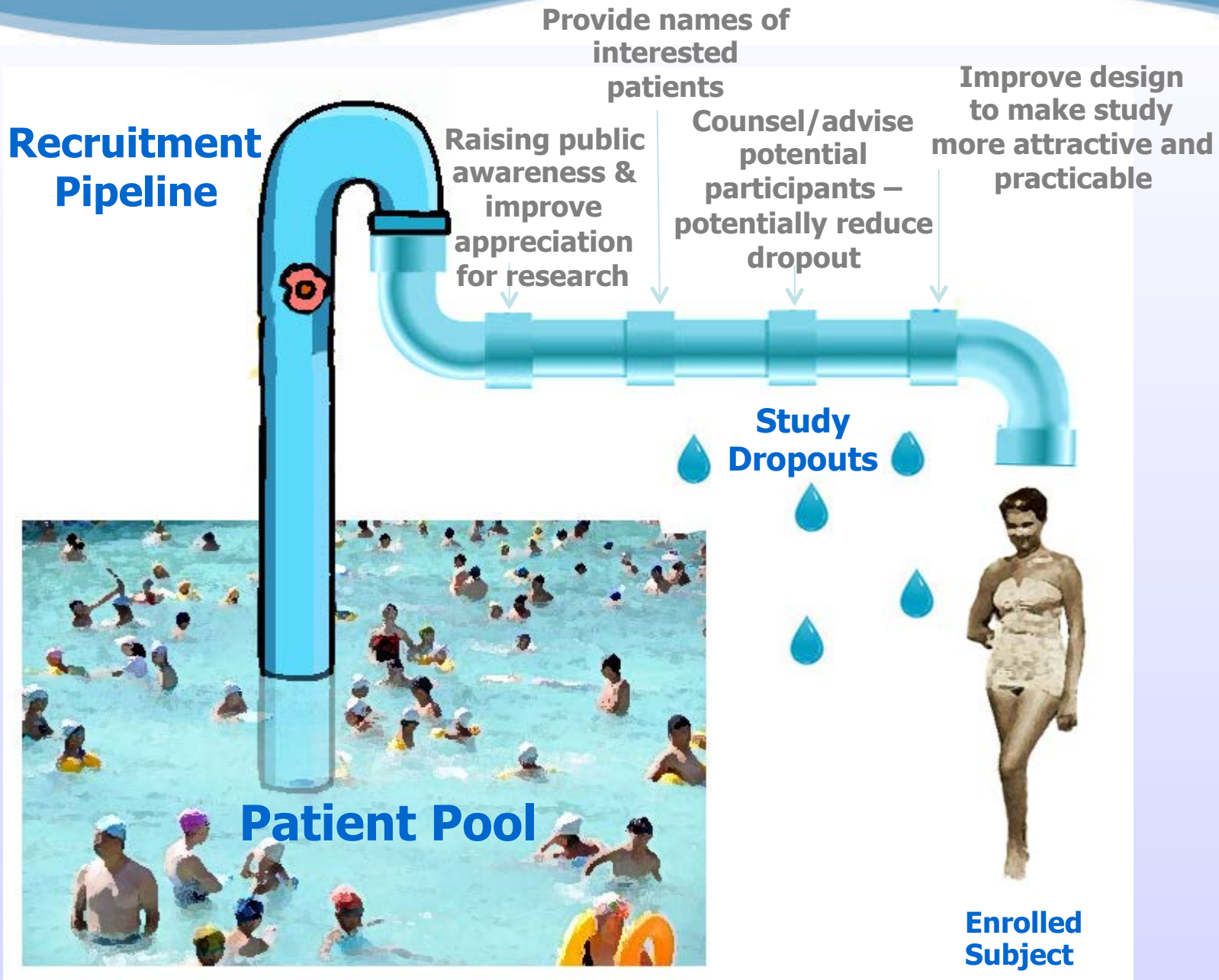
How can patients/advocates assist in trial recruitment?

- Contribute to more successful design that encourages greater recruitment
- Raising awareness of importance of trials
- Raising awareness about open clinical trials
- Match research-interested patients with studies (Patient registry/database)
- Provide disease-specific trial search mechanism
- Assist with prescreening (eligibility)
- Counseling and support


Provide names of interested patients
Improve design to make study more attractive and practicable
Recruitment Pipeline
Raising public awareness & improve appreciation for research
Counsel/advise potential participants – potentially reduce dropout
Study Dropouts
Patient Pool
Enrolled Subject

Code of Federal Regulations: Title 21 – Food and Drugs
SUBCHAPTER D--DRUGS FOR HUMAN USE

Part 312 – Investigational New Drug Application

(a) *Promotion of an investigational new drug.* A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

Informed Consent Information Sheet

Guidance for IRBs, Clinical Investigators, and Sponsors

SUMMARY OF THE CONSENT PROCESS

The consent process begins with subject recruitment, and it includes advertising used to recruit subjects into the clinical trial. Once a potential subject is identified, a person knowledgeable about the clinical investigation and capable of answering questions raised by the potential subject should conduct a consent interview.

IRB REVIEW OF ALL INFORMED CONSENT MATERIALS

IRBs must review all materials used in the informed consent process. This includes recruitment materials and information provided in addition to the informed consent document (for example, a chart explaining what to expect at each study visit or a document explaining the costs to subjects). The IRB's review is to ensure that information given to subjects as part of the consent process contains the elements identified in 21 CFR 50.25 and meets the requirements of 21 CFR 50.20 (see 21 CFR 56.109(a), 56.109(b), and 56.111(a)(4)).

REVIEW OF THE CONSENT PROCESS

The investigator should advise the IRB of the consent process to be used. The materials and procedures used for subject recruitment, which typically include advertisements, must be reviewed by the IRB to ensure that these materials are appropriate.

Recruiting Study Subjects - Information Sheet
Guidance for Institutional Review Boards

and Clinical Investigators

The IRB should also review the methods and material that investigators propose to use to recruit subjects.

Media Advertising:

Direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study, is not in and of itself, an objectionable practice. Direct advertising includes, but is not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects.

IRB review and approval may assure that the additional information **does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.**

Take-Aways

- FDA does not have any regulations specific to patient involvement in research subject recruitment
- Universal "dos and don'ts"

DO:

- **Clearly characterize studies as RESEARCH**
- **Stick to approved materials**

DON'T:

- **Suggest study as TREATMENT**
- **Characterize as SAFE**
- **Characterize as EFFECTIVE**