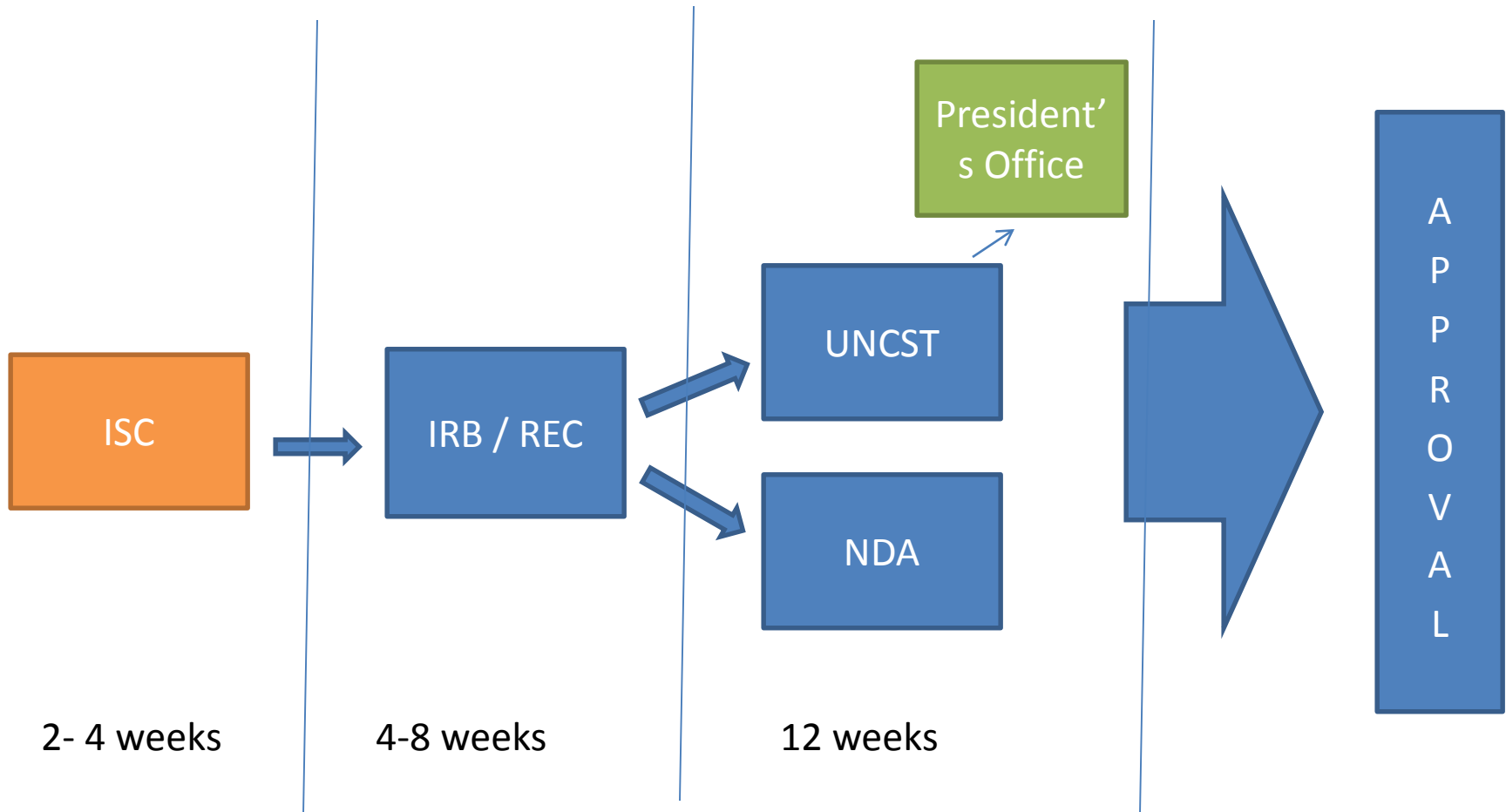


Research Involving Pregnant Women in Uganda

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Research regulatory system in Uganda



Regulatory

- UNCST regulations considers Pregnant Women to be among the vulnerable group .
- It also specifies that with respect to research among pregnant women and fetuses, prior appropriate research in Animal models and non-pregnant women should have been completed (**MTN-020 / ASPIRE**).

Regulatory

- During the consenting process, a statement - that a particular treatment or Procedure under study *may involve risk to the research participant or to the embryo or fetus if the research participant is or May become pregnant, and that the risk is Currently unforeseeable* – should be included.

Informed Consent by Pregnant Women

- For research involving pregnant women, informed consent should be obtained from both the mother and father of the embryos and fetuses.

Informed Consent by Pregnant Women

- However the father's consent Shall not be required if:-
 1. the purpose of the research is primarily to meet the health needs Of the mother;
 2. the father's identity and/or Whereabouts are unknown;
 3. the father is not reasonably available;
 4. the pregnancy resulted from rape or incest.
 5. the father Is incompetent to give consent

Informed Consent by Pregnant Women

- No provision of this subsection shall be construed as authorization to terminate a pregnancy where such termination would not otherwise be in conformity with current Laws of Uganda relating to the termination of pregnancy.

Local Context.

- Most studies involving pregnant women are often observational or behavioral intervention in natural
- The few clinical trials conducted are often directly towards pregnancy related health conditions like PPH,
- Some interventional studies (e.g MOMS) have been successfully conducted.

Local Context.

- Besides research, pregnant women are considered “a special population” and generally respected and taken to be “delicate” by the society.
- Male partners play a role in women’s decision hence their involvement is important.

THANK YOU