


**EXTENDED FOLLOW-UP IN  
MULTI-PHASE CLINICAL TRIALS**



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**OUTLINE**

- Extended Follow-up
- Common Challenges
- Strategies for Facilitating Recruitment
- Ethical Considerations
- Questions or Comments

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**WHAT IS EXTENDED FOLLOW-UP?**



The monitoring of a population or cohort over an extended period of time to evaluate the progression of a single variable, or to evaluate different effects of an intervention on that group

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**WHAT IS THE VALUE?**

Learn more about the study population	Strengthen previous objectives by gathering relevant data
Identify and study the impact of the intervention on various subgroups of the population	Understand the long-term effects or efficacy of an intervention

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**LAYING THE FOUNDATION**

Important considerations in the first phase:

- Informed consent and assent forms
- Record keeping
- Characteristics of the population
- Geographic coverage and feasibility

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**COMMON CHALLENGES**

- Mobile population
- Staff turnover
- Offsite Records
- Participant removed from clinical setting for several years
- Differing REB/IRB protocols across study sites

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**SITES WITH A MOBILE POPULATION**



Maintain contact information



Send out reminders



Establish a satellite clinic



Offer a home visit



Reimburse participants

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**STAFF TURNOVER**

Maintain logs with:

- Record of each participant's visits
- Record of contact with each participant
- Important considerations regarding the participant's health and ongoing trial involvement

Arrange for outgoing and incoming staff to meet

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**OFFSITE RECORDS**

- Increasing use of offsite record management services and storage facilities
- Keep charts or copies of information on-site when recruiting participants
- Ensure that a full record of study enrollment and updated information is added to patient charts for future reference

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### SITE LOG

	A	B	C	D	E	F	G	H	I	J	K
1	Study Title										
2											
3											
4											
5	Patient ID		Medical condition	Previous	Name and	Target	Notes:	Consent			
6	Number	Name	or criteria for	follow-up	contact	for next of	assessment	Status of	forms		
7		DOB	eligibility	In Study X	Info	kin	date	Contact	received		
8	kxxxx	John Smith	07-Sep-95				22-May-12		Yes		
9											
10											
11											

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### CONTACTING PARTICIPANTS

There can be a discrepancy across study sites regarding the use of:



Directories  
(online or print)



Social  
Media



Physician's  
Offices



External  
Services

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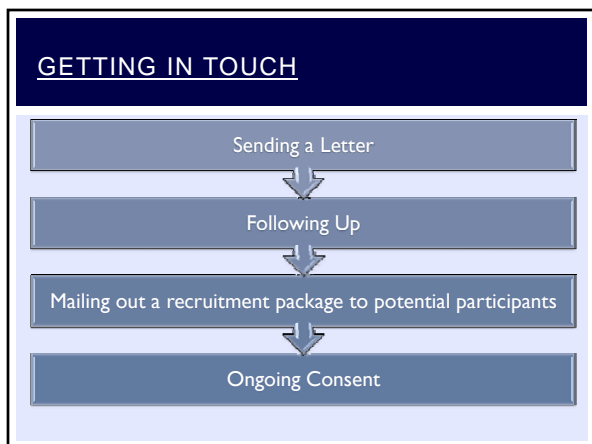
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### CONTINUITY OF CONTACT

Long serving members of the study team can be extremely helpful in extended follow-up by:

- Providing direction
- Maintaining successful processes
- Keeping consistent records
- Familiarity with sensitive participant/family situations



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### KEEPING PARTICIPANTS INFORMED

Certain phases or assessments in the trial may be of greater interest to participants than others

Informing participants of upcoming assessments, and their purpose, can increase receptivity and encourage participants to maintain contact

- Newsletters
- Reminder cards
- Verbal reminders at each appointment

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### ETHICAL CONSIDERATIONS

REB/IRB restrictions on contacting participants

Challenging family or personal circumstances, particularly those involving pediatric or other vulnerable populations

Degree of parental involvement in decision to participate

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THANK YOU!

Questions or Comments?

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