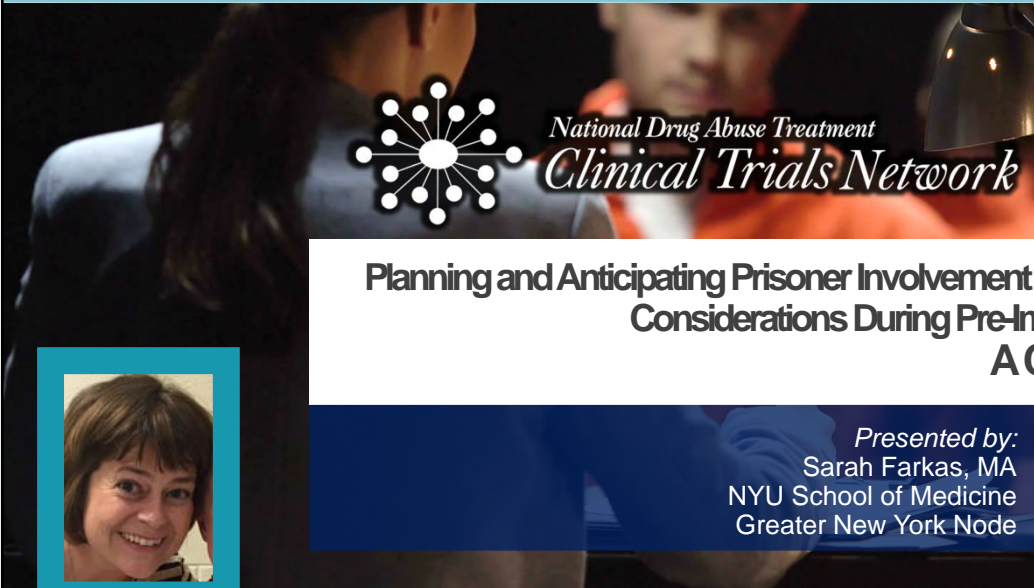


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National Drug Abuse Treatment
Clinical Trials Network

Planning and Anticipating Prisoner Involvement in a Clinical Trial Considerations During Pre-Implementation – A Checklist Tool



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Greater New York Node



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Discussion Objective

Outline the steps a study team should consider to include prisoners post-enrollment


Planning and Anticipating Prisoner Involvement in a Clinical Trial
Considerations During Pre-Implementation – A Checklist Tool





Time is essential – Plan for as much as possible during study pre-implementation

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Proactive

~~Reactive~~

Planning for approval early is critical

- Less potential for missing data
- Less of a regulatory burden

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Considerations During Pre-Implementation – A Checklist Tool



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Planning for Prisoner Engagement – A Checklist Tool	
Selection of Single Institutional Review Board (sIRB)	<input type="checkbox"/> What is the sIRB's experience with research including prisoners and the OHRP Prisoner Certification process? <input type="checkbox"/> What is the typical length of time for approval to be issued by IRB and OHRP? <input type="checkbox"/> How many prisoner advocates are on the IRB? Are they voting members? <input type="checkbox"/> How often does the Board meet and include the prisoner advocate?
Protocol Document Development	<input type="checkbox"/> Prisoners will not be enrolled <input type="checkbox"/> Treatment and follow-up procedures may be continued, in accordance with IRB approval <input type="checkbox"/> Data may be collected either in person, by phone, in writing, and/or by electronic means <input type="checkbox"/> Details or nature of the research will not be shared with staff at the jail/prison <input type="checkbox"/> Visits—whether in person or by phone—will only be conducted if the participant's confidentiality can be maintained; no audio-recording
Informed Consent Document Development	<input type="checkbox"/> Study team will want to follow-up with participant should he or she become a prisoner <input type="checkbox"/> Continued study participation has no effect on judicial proceedings <input type="checkbox"/> Interview will only take place if confidentiality can be maintained (no audio-recording) <input type="checkbox"/> Include language on compensation
sIRB Approval Submission (process considerations)	<input type="checkbox"/> DHHS recommends that research involving prisoners is reviewed by the <u>Full Board</u> > Initial submission must be reviewed by the Board with the prisoner advocate > IRB determines prisoner classification > Approval letter issued <input type="checkbox"/> Submission to sIRB for approval 4-5 weeks (maybe more depending on the sIRB) **OHRP review and approval must be obtained prior to opening study enrollment** <u>OHRP Approval Process</u> <input type="checkbox"/> OHRP must review and concur with determination made by the sIRB <input type="checkbox"/> OHRP issues approval letter to sIRB, concurring with prisoner classification <u>Back to sIRB</u> <input type="checkbox"/> sIRB provides study team with OHRP approval letter for inclusion in the Regulatory Binder Study Enrollment May Begin!



Pre-Implementation

Considerations during planning

- Selection of Single Institutional Review Board (sIRB)
- Protocol Document Development
- Informed Consent Form
- Approvals Processes

Planning for Prisoner Engagement – A Checklist Tool

Selection of Single Institutional Review Board (sIRB)

Questions to ask prospective sIRB...

- What is the sIRB's experience with research including prisoners and the OHRP Prisoner Certification process?
- What is the typical length of time for approval to be issued by IRB and OHRP?
- How many prisoner advocates are on the IRB? Are they voting members?
- How often does the Board meet and include the prisoner advocate?

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Protocol Document Development

- Prisoners will not be enrolled
- Treatment and follow-up procedures may be continued, in accordance with IRB approval
- Data may be collected either in person, by phone, in writing, and/or by electronic means
- Details or nature of the research will not be shared with staff at the jail/prison
- Visits—whether in person or by phone—will only be conducted if the participant's confidentiality can be maintained; no audio-recording

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Informed Consent Form Development

- ❑ Study team will want to follow-up with participant should he or she become a prisoner
- ❑ Continued study participation has no effect on judicial proceedings
- ❑ Interview will only take place if confidentiality can be maintained (no audio-recording)
- ❑ Include language on compensation

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Planning for Prisoner Engagement – A Checklist Tool

sIRB Submission for Approval

Process considerations...

- ❑ DHHS recommends that research involving prisoners is reviewed by the Full Board
 - Initial submission must be reviewed by the Board with the prisoner advocate
 - IRB determines permissible category of research for prisoners
 - Approval letter issued
- ❑ Submission to sIRB for approval 4-5 weeks (maybe more depending on the sIRB)

****OHRP review and approval must be obtained prior to opening study enrollment****

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OHRP Approval Process

Process considerations...

- ❑ OHRP must review and concur with determination made by the sIRB
- ❑ OHRP issues approval letter to sIRB, concurring with the classification of research with prisoners

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Planning for Prisoner Engagement – A Checklist Tool

Single Institutional Review Board

Process considerations...

- ❑ sIRB provides study team with OHRP approval letter for inclusion in the Regulatory Binder

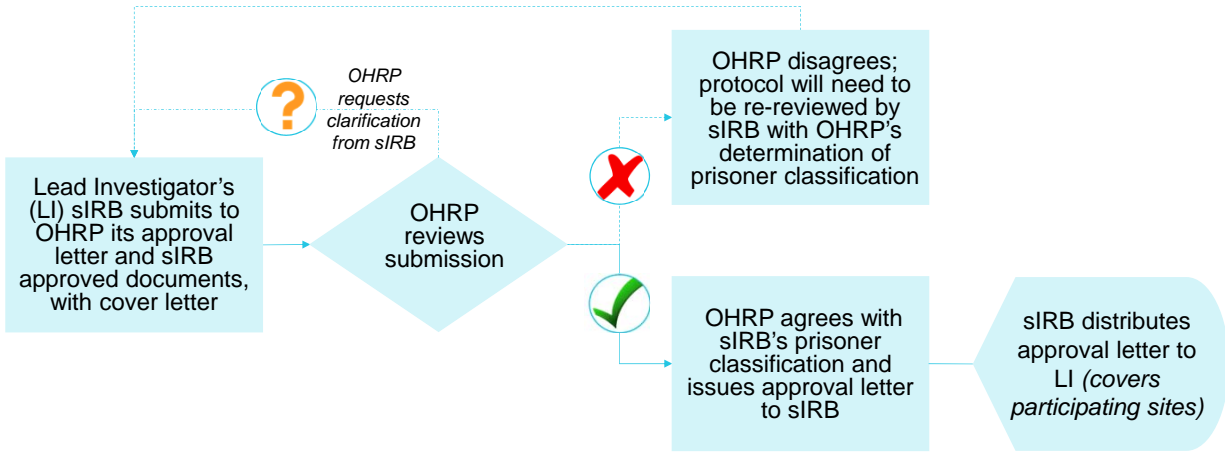
Study Enrollment May Begin!

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OHRP Prisoner Certification Review Process



Refer to OHRP's website at www.hhs.gov/ohrp for regulations and requirements on conducting research with prisoners

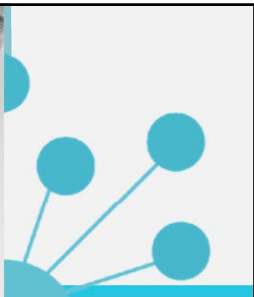


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Thanks for your participation.

