IRB Approval Checklist:
Return of Individual Research Results

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

	YES	NO	MORE INFO NEEDED	NOT APPLICABLE
The Study Protocol and/or Informed Consent Form (ICF) describes the plan for returning individual research results (IRR). If there is no intention to return IRR, plans and procedures in the event of urgent or incidental findings are still outlined. **The following is included in the Study Protocol:**				
Whether results will be returned	☐	☐	☐	☐
Which results will be returned	☐	☐	☐	☐
How results will be returned	☐	☐	☐	☐
Document templates and/or a website portal will aid in communicating results to participants and were included with submission	☐	☐	☐	☐
When results will be returned	☐	☐	☐	☐
Who will return and receive results	☐	☐	☐	☐
Healthcare provider contact information will be collected if necessary	☐	☐	☐	☐
Procedure in place for results returned to parent/guardian or Legally Authorized Representative	☐	☐	☐	☐
Designee (close friend or family member) to contact in case the participant is not reachable or available	☐	☐	☐	☐
Designee to contact in case the participant is deceased	☐	☐	☐	☐
Appropriate provisions are included for urgent results or urgent incidental findings that may occur during the study and *must* be returned	☐	☐	☐	☐
In the case of non-urgent findings, the participant or their legally authorized representative is able to make an informed choice as to whether to receive their individual results or not.				
Participants are given the choice whether or not to receive the information	☐	☐	☐	☐
There is a plan/system for tracking participant decisions	☐	☐	☐	☐
Participants will be consented or re-consented as needed when the results are available	☐	☐	☐	☐
Procedures for communicating results are respectful of the wishes of the participants	☐	☐	☐	☐

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	YES	NO	MORE INFO NEEDED	NOT APPLICABLE
Risks to participants from receiving their individual results are minimized by using procedures that are consistent with sound research design.				
Results will be validated (considering medical significance, analytical validity and medical actionability) to prevent ambiguous or incorrect information from being returned to participants	☐	☐	☐	☐
Plans are in place for confirmatory testing, clinical follow up, and counseling if appropriate	☐	☐	☐	☐
How to access follow-up care and resources, and how costs and charges will be paid, are explained to the participant	☐	☐	☐	☐
Attention is paid to potential psychological impact, as well as the method of communication with participants.	☐	☐	☐	☐
Genetic counseling is offered, if appropriate, and any associated costs to the participant have been outlined	☐	☐	☐	☐
Risks of IRR have been adequately addressed and minimized	☐	☐	☐	☐
Risks to participants from returning results are reasonable in relation to potential benefits and the importance of what may be learned from the research. **Risks include any physical, psychological, social, legal, and economic risks to participants from the return of their data.**				
Risks are clearly communicated in the informed consent form to research participants	☐	☐	☐	☐
Benefits are appropriate and not overly stated	☐	☐	☐	☐
Procedures and/or safeguards are in place to ensure that benefits can be realized, meaning participants have the ability to act on actionable information.	☐	☐	☐	☐
Possible benefits of the information (e.g. clinical action, knowledge) outweigh the risks of disclosure (e.g. false positive results, psychological stress)	☐	☐	☐	☐
Plan is in place for handling an adverse event related to receiving IRR (e.g., identifying site staff to provide requisite support, providing psychological or genetic counseling, informing the participant's HCP, etc.)	☐	☐	☐	☐

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	YES	NO	MORE INFO NEEDED	NOT APPLICABLE
Selection of participants for receipt of individual results is equitable.				
All participants (e.g., consented and/or randomized) are offered their information	☐	☐	☐	☐
No participants are excluded from access to information without appropriate justification	☐	☐	☐	☐
If returning the research results could involve more than minimal risk to participants, the communication plan includes adequate provisions for how the participants will be monitored to ensure participant safety.	☐	☐	☐	☐
There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of individual participant data.	☐	☐	☐	☐

REVIEWER'S COMMENTS

Note changes the investigator must make to meet certain criteria or specify additional information needed to help you decide whether a criterion is met.