IRB Standard Operating Procedure for Handling Revocation of Consent or Other Participant Complaints

SCOPE
These guidelines apply to all employees in the Office of Human Subjects Protection (OHSP)

PURPOSE
The purpose of this standard operating procedure (SOP) is to provide guidance on how to handle requests for revocation of consent or any other participant complaints regarding their participation human subjects research.

DEFINITIONS
IRB – Institutional Review Board
PDOL – Protocol Document On-Line
QA – Quality Assurance
PI – Principal Investigator
SOP – Standard Operating Procedure

PROCEDURE
Please document in the medical records, research record, and send a confirmation letter to the home IRB via PDOL.

When a participant or his/her representative informs the Office of Human Subjects Protection (OHSP) staff verbally or in writing, that (s)he wishes to revoke consent to a human subjects research protocol and/or to discuss a complaint involving their participation in the research, the following information is obtained:

1. Participant calls the IRB contact phone number listed in the informed consent document and is transferred to the Director, IRB Manager, IRB Supervisor or Quality Assurance Specialist (OHSP staff).

2. The OHSP staff member will confirm participant’s wish to revoke consent to applicable human subjects research protocol and/or document participant complaint. Participant information (name, medical record number & contact information) is collected by the IRB staff member and is provided immediately to Principal Investigator (PI) by email or phone or to the appropriate contact person. The OHSP staff member’s contact information is provided to the participant or his/her representative.
3. If revocation request is received from the participant’s representative in the participant’s absence, the name, relationship of that individual to the participant, and his/her contact information should be collected and provided to the PI or appropriate contact person.

4. The OHSP staff member will communicate the participant’s revocation request to the PI via email or phone communication and will request that documentation be provided back to the IRB confirming that the participation revocation was completed. The PI will need to document in the medical records, research record, and also send a confirmation memo to the home IRB via PDOL.

5. The OHSP staff member will also request that the PI follow-up with the participant regarding completion of revocation process and any protocol withdrawal procedures that need to be followed. Confirmation will also be provided as to whether or not any unused samples will now be destroyed or returned to the respective banks.

6. If the patient is requesting revocation from a protocol that has a Genome-wide Association Study (GWAS) certificate, then the PI must confirm if distributions have been made or not. If data has already been distributed it cannot be retrieved.

7. Complaints and concerns expressed by the participant or his/her representative regarding any human subjects research protocols are documented and conveyed to the IRB Chair via Outlook email. The IRB Chair will review to determine if additional actions are required. The OHSP staff member will communicate the IRB Chair’s determination to the PI.

8. Once the OHSP staff member receives written confirmation from PI regarding completion of revocation of consent, the documentation will be filed in the hardcopy protocol folder.

**ESCALATION PROCESS**

For participants who are upset or anxious the OHSP staff member will refer these participants directly to the IRB Chair, OHSP Director, or IRB Manager for immediate assistance. The following steps will occur:

A. The IRB Chair, OHSP Director, or IRB Manager will speak to the participant to understand the concerns.

B. The IRB Chair, OHSP Director or IRB Manager will document those concerns.

C. If a complaint is made with regards to the conduct of the study, the IRB Chair, the Institutional Official, and Institutional Compliance Office will be consulted for guidance. Formal documentation to the participant may be provided from the convened IRB and/or the Institutional Official with guidance provided by the Institutional Compliance Office.

D. If a complaint is made with regards to the IRB, the OHSP Director and IRB Manager will conduct a preliminary review and provide their assessment to the Institutional Official. The Institutional Official will determine how to address the concern in consultation with the OHSP Director, IRB Manager and/or Institutional Compliance Office. Depending on the nature of the complaint, a formal, written documentation may be submitted to the Executive IRB in consultation with the Institutional Official and Institutional Compliance Office. Other institutional offices may be conferred with as needed.

E. If a complaint is made with regards to research participant billing, the OHSP Director and IRB Manager will consult with the Executive Director, Clinical Research Finance
to conduct a preliminary assessment to gather relevant information, and provide an assessment and/or recommendation to the IRB Chair and Institutional Official.

Depending on the nature of the complaint, guidance may be requested by other offices to provide guidance including: Institutional Compliance Office, Patient Business Services Executive Director, Risk Management, Patient Advocacy, Executive Session Chair.

A formal documentation will be provided to the participant from one of these groups depending on the nature of the complaint.

The PI will be required to maintain a log of each participant complain in their regulatory binder.

Revolvervation of Consent by Participant

Once the OHSP Director, IRB Manager or IRB Supervisor confirms the participant’s wish to revoke consent to an applicable human subjects research protocol, a detailed note documenting the participant’s complaint or request is forwarded to the QA Specialist and the Program Coordinator. Once received, each incident is recorded and tracked on the Patient Complaint Log, Appendix A. The template indicates all of the information that should be collected from the caller including items such as: participant name, person making the call, PI, protocol number, protocol title, and a summary of the event.

The IRB Manager or IRB Supervisor may also request the PI and/or study team to provide a written report of the incident with action items. The QA specialist or Program Coordinator will follow-up on all action items through resolution.

A quarterly report that includes actions taken on any of the actions listed above will be provided to the Institutional Official and the IRB Chairs meeting (e.g., every 3rd Monday of the month).

**REFERENCES**

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Initials</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>11-30-15</td>
<td>Update</td>
<td>MBO</td>
<td>Updated SOP to include in new template.</td>
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<tr>
<td>12-8-15</td>
<td>Update</td>
<td>MBO</td>
<td>Included an escalation process; modified to state that IRB staff would participate in this process.</td>
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<tr>
<td>12-28-15</td>
<td>Update</td>
<td>NN</td>
<td>Included QA process.</td>
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<tr>
<td>9-6-16</td>
<td>Update</td>
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<td>Updated SOP to include WAS procedures</td>
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<tr>
<td>11-1-18</td>
<td>Update</td>
<td>LG</td>
<td>Updated Department Name from OPR to OHSP and other administrative changes</td>
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<tr>
<td>11-7-18</td>
<td>Update</td>
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<td>Administrative Changes</td>
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