Post-Approval Reporting to the Boston Medical Center and Boston University Medical Campus IRB
**Also applies to Ceded Studies

Information	Description	Form to use	When to Report
1. Planned change to study	A plan to modify an approved procedure or document (protocol, funding, consent form, recruitment material, etc.) *except* study personnel (see 2. below) or contact information only (see 3. below)	**Change Request & Amendments** *OR* **Protocol Exception** (if for one-time change to approved protocol, such as enrolling a subject outside the approved inclusion criteria)	In enough time to receive approval prior to making the change
2. **Changing study personnel	A plan to add or remove study team members	**Internal Study Personnel Changes**	In enough time to receive approval prior to making the change
3. Changing contact information	A plan to change contact information only on consent forms and/or other subject material	**Contact Information Change Request**	In enough time to receive approval prior to making the change
4. Progress report	Required information for re-approval of the study	**Continuing Review Submission**	30 to 45 days prior to study expiration/status check-in due date
5. Final report	Required information for closing a study	**Final/Closure Report**	When human subject research activities have ceased
6. **Unanticipated Problem **occurring locally	An event that qualifies as an Unanticipated Problem (event was unexpected AND related/possibly related AND suggests greater risk, see definitions below) – whether or not it is also an Adverse Event or Serious Adverse Event	**Reportable Events and New Information** *AND* **Change Request & Amendments** addressing needed changes	Within **7 days** of the PI learning of event As soon as practical
7. Safety Monitors' Reports **with** recommended changes	DSMB reports, Data Monitoring Committee reports, Adverse Event Monitoring Committee reports, audit reports, etc. **with** recommendations for changes to the study	**Reportable Events and New Information** *AND* **Change Request & Amendments** addressing needed changes	Within **7 days** of the PI receiving the recommendations As soon as practical
8. Major Deviations	Noncompliance with IRB requirements that may be serious or continuing, or an unapproved change in the research study design or procedures that may affect the participant's rights, safety or well-being and/or may affect the overall reliability of the study data.	**Reportable Events and New Information**	Within **7 days** of the PI learning of the deviation

9. Adverse Events that are NOT Unanticipated Problems	All Adverse Events and Serious Adverse Events (see definitions below) that do *NOT* qualify as an Unanticipated Problem (event was expected *OR* unrelated *OR* suggests no new risk).	**Continuing Review Submission**: • Section 4: If there is a Data Safety Monitoring Board (DSMB), attached DSMB report satisfies AE reporting • Section 5 if no DSMB (AE/SAE summary report – see #11)	At the time of Continuing Review/ Status Check-in
10. Safety Monitors' Reports **without** recommended changes	DSMB reports, Data Monitoring Committee reports, Adverse Event Monitoring Committee reports, audit reports etc. **without** recommended changes to the study	Attached to **Continuing Review Submission** Section 4 (The most recent report must be attached)	At the time of Continuing Review/ Status Check-in
11. AE/SAE Summary Report	Summary of all adverse events (including AE and SAEs) that have occurred since last continuing review/ check-in - must include PI's conclusion that the pattern of events does not suggest a greater risk of harm	Attached to **Continuing Review** Section 5 (Not required if there is a formal DSMB report)	At the time of the Continuing Review/ Status Check-in
12. Minor Deviations	Noncompliance with IRB requirements and/or unapproved changes in the research study design and/or procedures that do not have a major impact on the participant's rights, safety or well-being, or on the overall reliability of the study data.	Summary attached to **Continuing Review** Section 5	At the time of the Continuing Review/ Status Check-in
13. Lapse in study approval	**IF** human subject research activities occurred after the approval expiration date – MAJOR deviation (see #8)	**Reportable Events and New Information**	Within **7 days** of the PI learning of the lapse
	OTHERWISE (no intervention or interaction with subjects and no analysis of identifiable information) – minor deviation (see #12)	Attached to **Continuing Review** Section 5	At the time of the Continuing Review/ Status Check-in

Definitions

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research**.**

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or

(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents (such as the IRB-approved research protocol and informed consent document); and (b) the characteristics of the subject population being studied; AND
- is related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.