BRANY

Information Sheet for Researchers – EXTERNAL (off-site) ADVERSE EVENTS

What external (off-site) adverse events must be reported to BRANY IRB?

- Reports involving **external events (those occurring outside the local investigator's site)** should only be reported to BRANY IRB when a determination has been made that the events meet the criteria for an unanticipated problem involving risks to subjects or others.

  When an investigator receives a report of an external adverse event, the investigator should review the report and assess whether the adverse event is:

  (1) unexpected, and

  (2) related or possibly related to participation in the research, and,

  (3) serious, or otherwise suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

  Only external events that meet all three criteria must be reported promptly by the investigator to the IRB as unanticipated problems under HHS regulations at 45 CFR 46.103(b)(5). Unrelated external adverse events do not require reporting to the IRB.

  See section III.1.i. of BRANY IRB's policy for specific procedures for reporting unanticipated problems involving risks to subject or others.

What's the timeline for reporting qualifying external events to BRANY IRB?

- Investigators are required to notify the IRB **promptly, but no later than 5 days after the Investigator's first knowledge**, of any unanticipated problems involving risks to subjects or others that occur in research (45 CFR 46.103(b)(5), 21 CFR 56.108(b) and 21 CFR 312.66).

Which form do I use to report the above to BRANY IRB?

- The **Reportable Event Form** (xForm #16) is an electronic submission form available only through BRANY IRB's *IRBManager* web portal (link to IRBManager Login).

  Reports to BRANY IRB must contain a sufficient amount of information to permit the reviewer to judge whether the event raises new questions about risks to participants. Additional relevant documents should be included, as necessary.

  Report Contents
  - A detailed description of the incident
  - Indication as to whether the reported event placed any subject at risk
  - Indication as to whether the reported event affected the integrity of the study data
  - A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the reported event, when applicable
  - Information regarding changes implemented by the study team to ensure that such a reported event will not occur in the future, when applicable.

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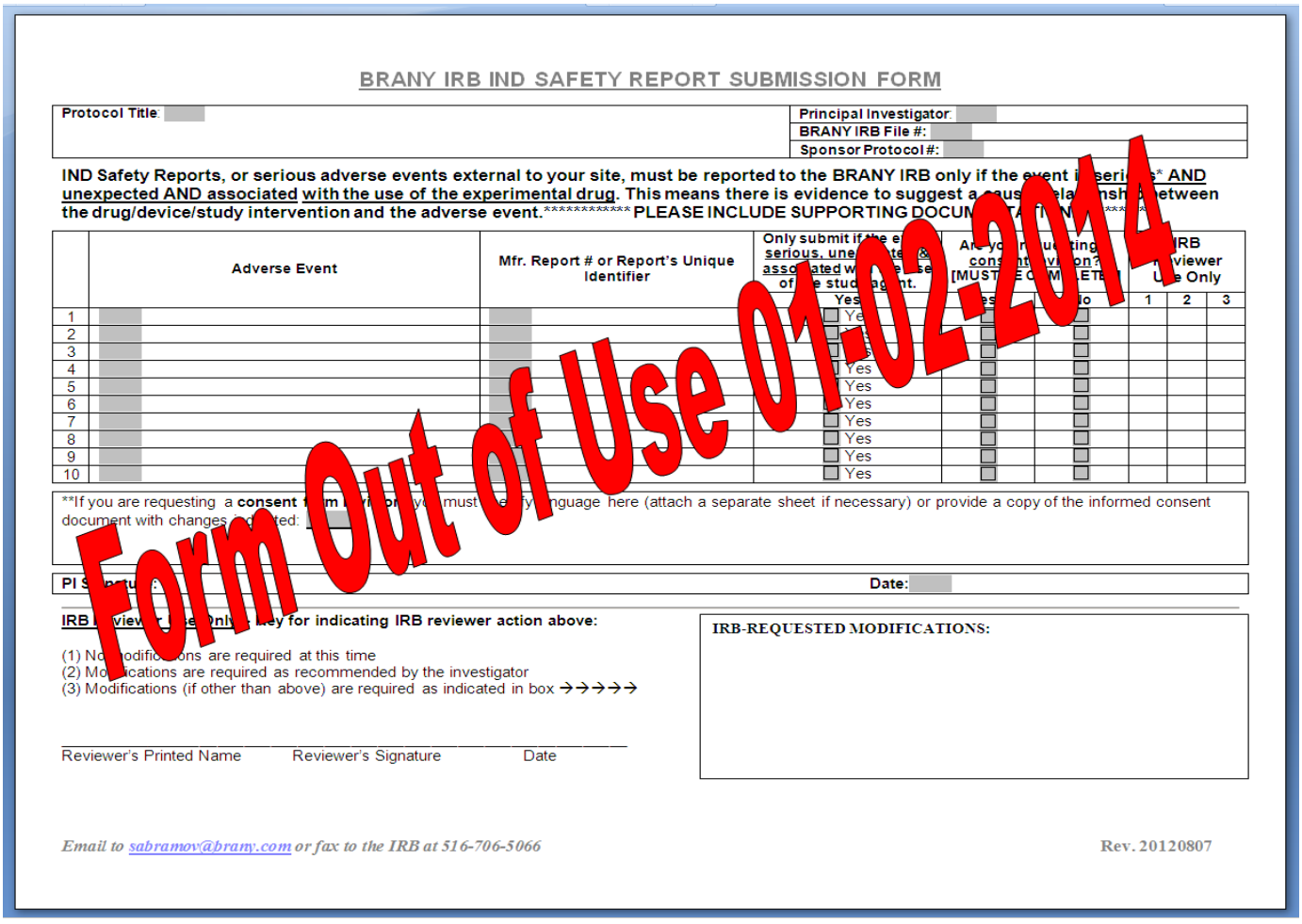
Should I still use the IND Safety Report Submission form to report external adverse events to BRANY IRB?

- No. **The IND Safety Report Submission form will no longer be accepted after 1/02/2014.** Any IND Safety Report Submission forms received prior to that date will be processed. Any IND Safety Report Submission forms received on or after 1/02/2014 will be returned to you. Please provide this information sheet to any party requesting documentation of the change in this requirement.



BRANY IRB IND SAFETY REPORT SUBMISSION FORM

Protocol Title:	Principal Investigator:
	BRANY IRB File #:
	Sponsor Protocol #:

IND Safety Reports, or serious adverse events external to your site, must be reported to the BRANY IRB only if the event is serious* AND unexpected AND associated with the use of the experimental drug. This means there is evidence to suggest a causal relationship between the drug/device/study intervention and the adverse event.********** PLEASE INCLUDE SUPPORTING DOCUMENTATION **********

	Adverse Event	Mfr. Report # or Report's Unique Identifier	Only submit if the event is serious, unexpected & associated with the use of the study agent.	Are you requesting consent revision? [MUST BE COMPLETED]		IRB Reviewer Use Only		
			Yes	Yes	No	1	2	3
1			Yes					
2			Yes					
3			Yes					
4			Yes					
5			Yes					
6			Yes					
7			Yes					
8			Yes					
9			Yes					
10			Yes					

If you are requesting a **consent from [illegible] must [illegible] language here (attach a separate sheet if necessary) or provide a copy of the informed consent document with changes [illegible]:

PI Signature: Date:

IRB Reviewer Use Only – Key for indicating IRB reviewer action above:

(1) No modifications are required at this time
(2) Modifications are required as recommended by the investigator
(3) Modifications (if other than above) are required as indicated in box →→→→→

Reviewer's Printed Name Reviewer's Signature Date

IRB-REQUESTED MODIFICATIONS:

Email to sabramov@brany.com or fax to the IRB at 516-706-5066

Rev. 20120807

Form Out of Use 01.02.2014

Who do I call if I have a question?

- Any questions or feedback may be directed to Raffaella Hart, CIP at rhart@brany.com or by calling 516-470-6909.