PREGNANCY REPORT FORM

SITE INFORMATION

Kirby Protocol Number: VHCRP1701 EDURACT Number: 2017-000694-37

To: Kirby Institute, VHCRP Fax No: +61 2 9385 9214 Email: smartc@kirby.unsw.edu.au

To: AbbVie Email: PPDINDPharmacovigilance@abbvie.com

Pages:_____ ☐ Initial Report ☐ Follow-up report Date of report *(dd/mon/yyyy*): ____/_____/_____

Principal Investigator's Name: _____ Reported By: _____

Site Phone Number: _____ Site Fax No: _____

PAARTICIPANT

Subject ID Number: 1701-__ __ __ __ __-__ __ Subject date of birth *(dd/mon/yyyy)*: ____/ _____/ _____ Initials: __ __-__ __

Date site became aware of pregnancy *(dd/mon/yyyy)*: ____/ _____/ _____

Estimated date of delivery *(dd/mon/yyyy)*: ____/ _____/ _____

Date of last menstrual period *(dd/mon/yyyy)*: ____/ _____/ _____

INVESTIGATOR SIGN-OFF

I verify that the information contained in this PREGAGNCY REPORT FORM is accurate and compatible with the source documents.

Investigator Name (Please print): _____

Investigator Signature: _____

Date *(dd/mon/yyyy):* ____/ _____/ _____

Reported to IRB/REC/EC/HREC: ☐ Yes ☐ No. If no, why? _____

Note: Pregnancy form can be submitted without the investigator signature but must be signed and resubmitted once signature is complete.

KIRBY

Received date: _____ Received By: _____

PREGNANCY REPORT FORM

FETAL OUTCOME

1. Fetal outcome: *(for multiple births, please complete a page for each infant)*

☐ Live infant *(complete 2-7)*

☐ Abortion, elective *(complete only 6 and applicable SAE form)*

☐ Subject refused to provide information

☐ Ectopic pregnancy *(complete only 6 and applicable SAE form)*

☐ Abortion, spontaneous *(complete only 6 and applicable SAE form)*

☐ Stillbirth *(complete 2-7 and applicable SAE form)*

☐ Lost to follow-up

2. Date of delivery *(dd/mon/yyyy)*: ____/ _____/ _____

3. Birth weight: _____ ☐ Lb ☐ Oz ☐ Kg

4. Birth length: _____ ☐ inches ☐ cm

5. Gender: ☐ Male ☐ Female

6. Medically significant complications during pregnancy/labor or delivery:

☐ No

☐ Yes, please describe:

7. Any birth defects: *(if YES, complete applicable SAE form)*

☐ No

☐ Yes, please describe: