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ICCTG PROTOCOL #1

Unmasking Record

Patient ID: _____
 Patient Initials: _____
 Clinical Center: _____
 Contact Week: _____
 Date: ____ / ____ / ____
month day year
 RC ID: _____

(Research Coordinator completed) (Photocopies of this form with signature must be sent to the DCC.)

1. Date of unmasking: Date: ____ / ____ / ____
month day year

2. Time of unmasking: ____ : ____ (Military time)

3. Was the DCC contacted within 3 days of unmasking? ₁ Yes ₀ No

If **YES**, name of person contacted: _____

If **NO**, give reason: _____

4. Who unmasked the drug? ₁ P.I.
₂ RC
₃ Other

5. If unmasked by someone other than the P.I., was the P.I. contacted prior to unmasking?
₁ Yes ₀ No

If **NO**, give reason: _____

6. Why was the drug unmasked? ₁ Serious Adverse Event as recorded on AE/SAE form as AE # ____
₂ Other hospitalization
₃ Other, please specify: _____

Signature: _____
Principal Investigator

Date: _____
 Did the P.I. sign this form? ₁ Yes ₀ No

Place unmasked white drug label here:

Place unmasked green drug label here: