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| **Submission Instructions:**  Use this form to report to The Office of Ombudsman for Mental Health and Developmental Disabilities (OMHDD) pursuant to Minnesota Statute 245.92 and 245.94. Please check applicable box below.  ***Section 1.*** Must be completed and submitted by the University of Minnesota Human Research Protection Program to the OMHDD for new clinical drug trials conducted by the University of Minnesota Department of Psychiatry.  ***Section 2.*** Must be completed and submitted by the University of Minnesota Principal Investigator to [report death or serious injury of locally enrolled study participant in psychiatry clinical drug trial within 24 hours of the incident to the Ombudsman](#http://mn.gov/omhdd/reporting-death-or-serious-injury/). This Transmittal Form must be used as the cover page to the applicable Report Form available on the OMHDD website: <http://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp>  ***Section 3.***Must be completed and submitted by the University of Minnesota Human Research Protection Program to the OMHDD for notification of study closure. | | | | **This Section for IRB use Only** | |
| ***Section 1 to be completed by the Human Research Protection Program*** | | | | | |
| **Section 1. Notification of New Study** | | | | | |
| **UMN IRB Study Number:** | | | **Reviewing IRB (External IRB) Study Number:** | | |
| **Study Title:** | | | | | |
| **Principal Investigator Contact Information** | Name:       Phone:  Email:       Fax: | | | | |
| **Date Ceded to External IRB:** | | | **Initial Study Approval Date from External IRB:** | | |
| ***HRPP to submit this form to OMHDD via email with a copy to the local UMN Principal Investigator and Psychiatry Department Head.*** | | | | | |
| ***Section 2 to be completed by the Local UMN*** [***Principal Investigator***](http://www.research.umn.edu/irb/guidance/pir.html) | | | | | |
| **Section 2. Notification of Death or Serious Injury** | | | | | |
| ***See attached for report detail.*** | | | | | |
| **Signature:** | | **Title:** | | | **Date:** Today’s date. |
| ***PI must complete Section 2 and submit to OMHDD along with the*** [***required submission form***](#http://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp) ***within 24 hours of incident. Section 2 must be signed and dated by the PI and sent to OMHDD via eFAX: 651-797-1950 (preferred) or analog FAX: 651-296-1021. Submitted form must include completed Section 1 stamped by UMN Human Research Protection Program. Additional information on reporting can be found on the OMHDD website:*** [***http://mn.gov/omhdd/reporting-death-or-serious-injury/***](http://mn.gov/omhdd/reporting-death-or-serious-injury/) | | | | | |
| ***Section 3 to be completed by the Human Research Protection Program*** | | | | | |
| **Section 3. Study Closure** | | | | | |
| This submission serves as notification that the above referenced study has been closed at the University of Minnesota. | | | | | |
| **Date of Study Closure:** | | | | | |
| ***HRPP to submit this form to OMHDD via eFAX: 651-797-1950 (preferred) or analog FAX: 651-296-1021 with a cc to the local UMN Principal Investigator.*** | | | | | |