Guidance on Identifying Risk Factors for West Nile Virus (WNV) in Potential Living Donors

Ad Hoc Disease Transmission Advisory Committee

Dr. Michael Green, MD, MPH, Chair
June 24-25, 2013

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Background

OPTN living kidney donor medical evaluation policy implemented in February 2013

- Requires WNV testing for potential kidneys donors from endemic areas
- Confusion in the community regarding specifically who should be tested

Background

Living Donor Committee requested that the DTAC develop guidance to:

- Define “endemic areas” for exposure and infection
- Discuss testing options

Document Development

The DTAC formed a Work Group to develop this guidance:

- AST Infectious Disease Community of Practice representation
  - Reviewed discussion from 2010 Donor Derived Consensus Conference for Solid Organ Transplantation on WNV
- Reviewed FDA and CDC guidance on this topic for the blood community

Summary of Guidance

The document includes:

- Epidemiology and pathophysiology of WNV
- FDA approved testing options
- DTAC experience on potential transmissions to date
- Risk factors (geographic and seasonal)
- Who and when to test
- What to do with a positive donor test or history of WNV
- Exposure management

Summary of Guidance

- **Most WNV infections are asymptomatic**
  - Clinical evaluation will not effectively identify all infection
  - Lab testing recommended during periods of human WNV activity where donor lives, works, or travels
- **FDA approved screening = NAT**
- **Initiation of testing based on local human WNV activity informed by local blood bank results**
  - May allow centers to test only during periods when human disease is present
  - May reduce false positives and testing costs
- **Seasonal testing is an alternative, but not as cost effective**

If approved…

- Guidance document will be posted on the OPTN website as a professional resource

- Will be highlighted in UNOS Update and DTAC News e-newsletter

Resolution 2

RESOLVED, that the updated guidance document "Guidance for Identifying Risk Factors for West Nile Virus (WNV) in Potential Living Donors," set forth in Exhibit A to the DTAC's report to the Board, is hereby approved, effective June 25, 2013.

**Page 5 of Board book*

Questions?

Thank you.

Enhancements to the Disease Transmission Reporting Section of the Improving Patient Safety Portal in UNet℠

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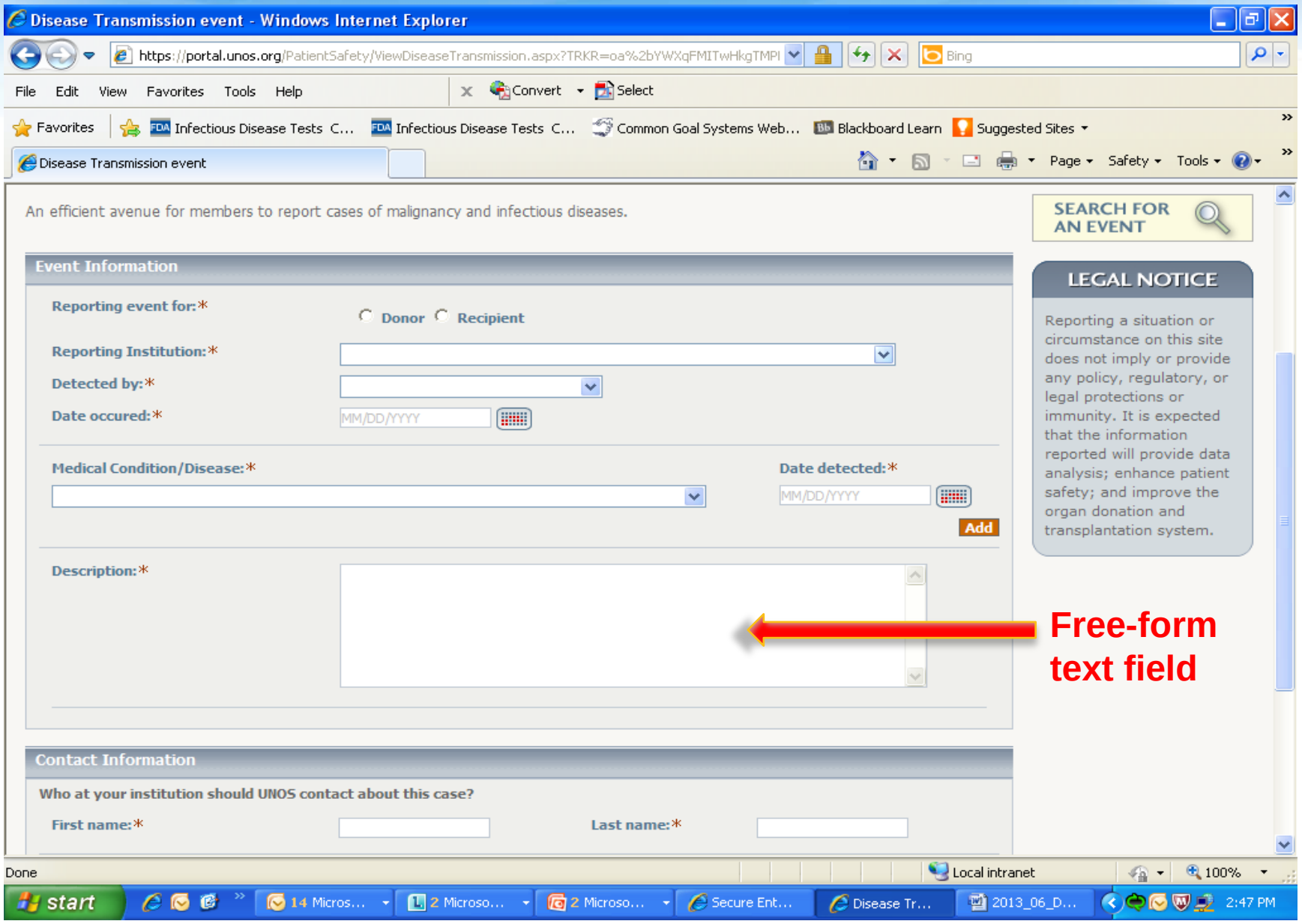
Current Reporting Relies on Open Text Field

- Little consistency in reporting
  - Some sparse, some very lengthy but not including the information DTAC needs to begin review of a potential transmission
- Inefficient for members
  - Time consuming to draft a narrative
  - Greater opportunity for errors or miscommunication
- Inefficient for staff
  - Can be difficult to glean the details needed by the DTAC without contacting the reporter for more information



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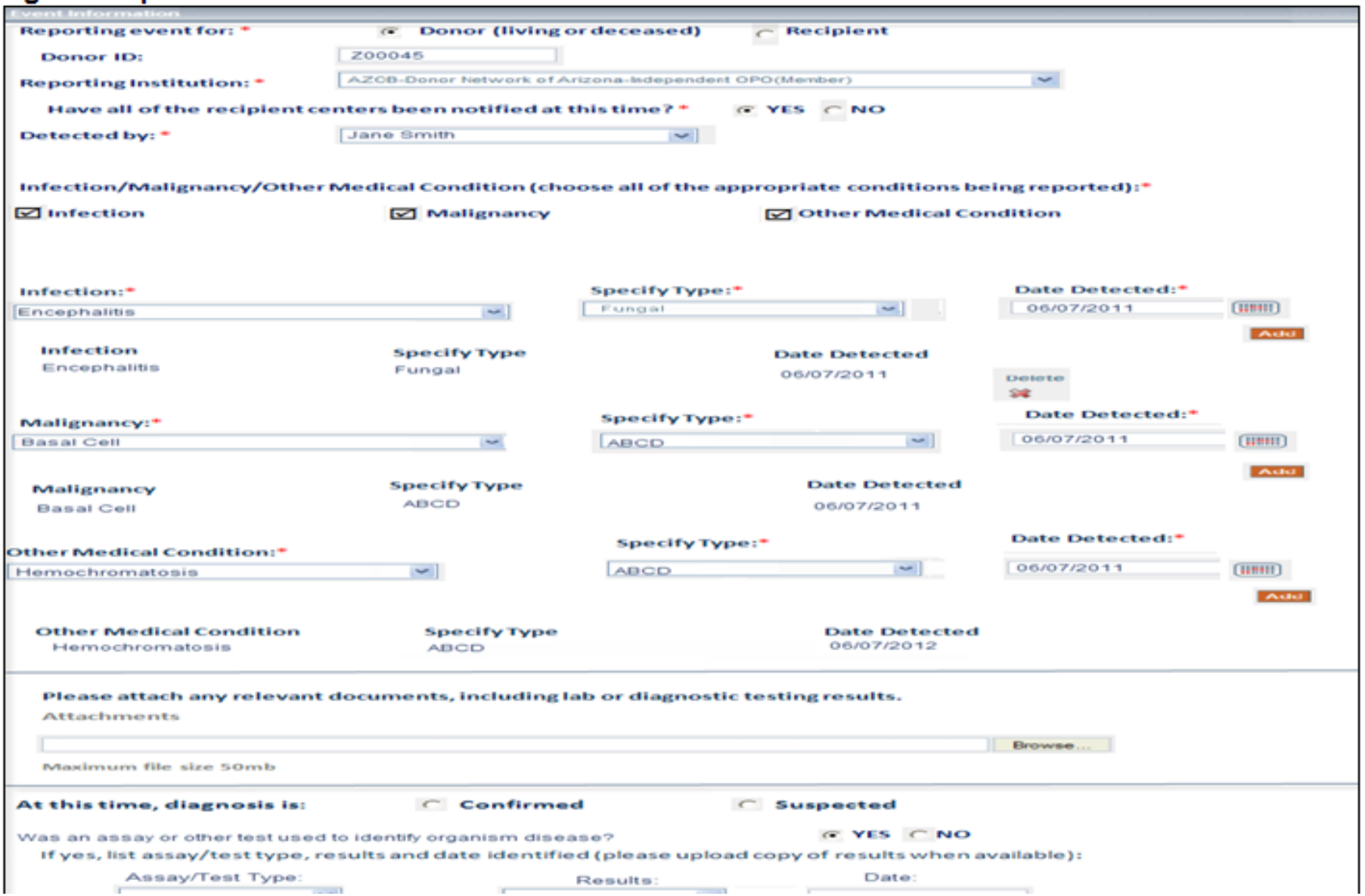
Proposed Modifications

- Prompts reporter for standard information needed in most potential transmission event reviews
- Incorporates many drop downs and pick lists for diseases and related testing
- Will allow for review of reported data in a more automated fashion within the Improving Patient Safety portal

Modifications expected to streamline reporting process for submitter and staff managing case review!

Figure 6 Expanded view Donor PDDTE



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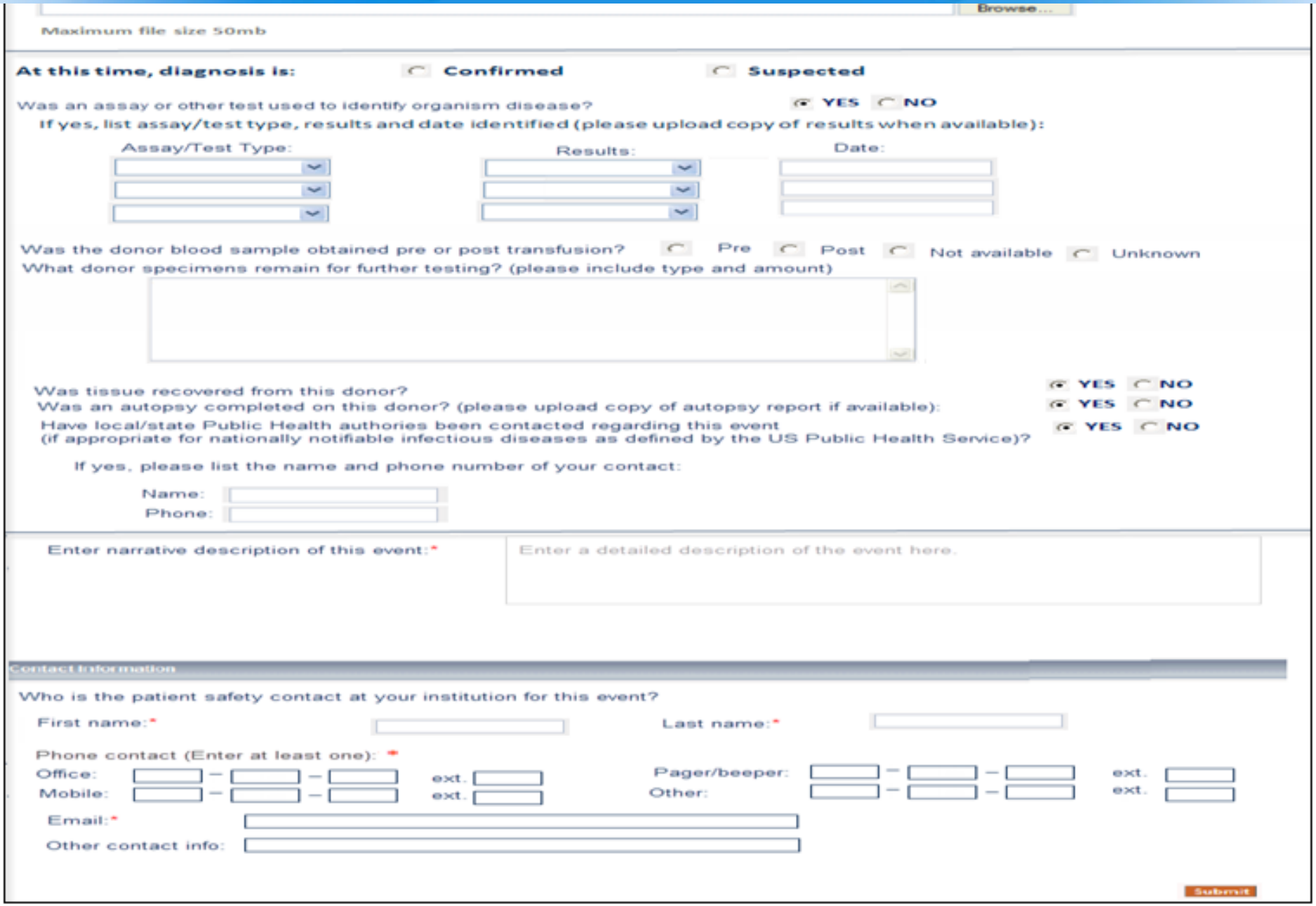

Note – The screen shot above is for illustration purposes only. The actual font type, size, color and alignment of elements

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Related Programming

- **Project Size = Large Effort**
  - 1570 hours estimated / $89,219 in cost
  - Bulk of time will be IT-related: 1430 hours
    - Split between programming, testing, and education (related to updating help documentation, system notice, etc)
- **Part 3 of 3 updates to the Improving Patient Safety Portal**
  - Operations & Safety updates for Patient Safety Situation reporting = very large effort (2580 hours / $146,848)
  - Living Donor Committee updates to Living Donor Adverse Event reporting = medium effort (730 hours / $43,155)

Expected Benefits

- For members submitting PDDTE reports
  - Easier to know WHAT to report rather than developing a narrative
  - Clicking various options MORE TIME EFFICIENT than drafting a narrative
- For UNOS staff managing cases
  - Information easier to process and prepare for DTAC review
  - Receiving the RIGHT information on the front end allows for expedited handling and communication to other recipient centers as needed

Overall, these modifications will allow for a more efficient process all users and enhanced patient safety!

Resolution 9

RESOLVED, that proposed enhancements to the Improving Patient Safety Portal for reporting potential donor-derived disease transmission events be programmed and implemented, effective pending programming and notice to the OPTN membership.

**Page 18 of Board book*

Questions?

Thank you.

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Factors to Consider During Living Donor Evaluation

- Has human infection with WNV virus been **recognized locally** this WNV season?
- Has the donor **travelled to an area with human WNV activity** this WNV season?
- Has the donor **ever been diagnosed** with WNV fever or WNV neuroinvasive disease?
- Has the donor had an **undifferentiated febrile illness** within the current WNV season?
- Has the donor had **significant mosquito exposure** this WNV season?