***Please note:*** *There will be a cross-core collaborative session at the Spring 2025 ADRC meeting including the Biomarker, Imaging, and Clinical Core Steering Committees which will focus on using biomarkers in UDSv4. Any feedback that we receive after this meeting and as well as any suggested changes that arise due to the evolving AD & ADRD biomarker field will be incorporated into a future draft of this form.*

**Explanation of the D1a and D1b Clinical and Etiologic Diagnosis Forms**

The ADRC uses the D1a form to document the *clinical diagnosis* and the D1b form to document the *etiologic diagnosis*. The purpose of these forms is to clearly indicate what information—clinical only or clinical with biomarker data—was used to make an etiologic diagnosis of dementia or cognitive impairment. This allows for a detailed understanding of whether the etiologic diagnosis was based solely on clinical assessments or if it was supported by biomarkers such as PET scans, CSF biomarkers, or blood biomarkers.

**Key Points:**

1. **Flexible Use**: ADRCs should have the flexibility to use these forms in a way that fits their specific processes and timelines. The forms are not intended to dictate when or how biomarkers should be collected or incorporated but to document whether biomarkers were considered when making the etiologic diagnosis.
2. **Timelines and Biomarker Data**: Given that biomarkers may return on different timelines, it is not always feasible to delay a consensus conference to wait for biomarker results. The forms are designed to capture the clinical judgment made at the time of the conference, regardless of whether biomarkers were available.
3. **Point-in-Time Documentation**: The forms are intended to record what information was used at the time of diagnosis. There is no need to update the forms later if biomarkers become available after the consensus conference. However, if biomarker data are incorporated in future clinical assessments, this should be documented on those new forms during those future assessments.

**Example Scenarios for Using the D1a and D1b Forms:**

**Scenario 1: Diagnosis Made Without Biomarker Support**

1. **Situation**: An ADRC holds a consensus conference to diagnose a patient who has undergone cognitive assessments and standard clinical evaluations, but biomarker data (such as an amyloid PET scan or CSF biomarkers) are not yet available.
2. **D1a Form**: The clinical diagnosis (e.g., probable Alzheimer's disease or mild cognitive impairment) is documented based on the clinical data available.
3. **D1b Form**: An etiologic diagnosis is assigned (e.g., Alzheimer's disease as the likely etiology), and it is explicitly noted that this diagnosis is *not* supported by biomarkers. The absence of biomarker data does not change the fact that an etiologic diagnosis is made and it is clear that this etiologic diagnosis was supported by clinical information alone.

**Scenario 2: Delaying Consensus Conference for Biomarker Data**

1. **Situation**: An ADRC is moving toward biomarker-supported diagnoses and has decided to wait several months for biomarker results (e.g., amyloid PET scan or CSF analysis) before holding a consensus conference.
2. **Process**: The site holds a consensus conference only after the biomarker data are available, using this data to support the etiologic diagnosis.
3. **D1a Form**: The clinical diagnosis is documented based on clinical data.
4. **D1b Form**: The etiologic diagnosis is documented as *supported* by biomarkers, clearly indicating the information that influenced the diagnosis.

**Scenario 3: Biomarker Data Available but Not Used**

1. **Situation**: A site has collected biomarker samples or data but is not yet ready to use it for diagnosis. A consensus conference proceeds without waiting for these results.
2. **D1a Form**: The clinical diagnosis is documented based only on clinical data.
3. **D1b Form**: The etiologic diagnosis is assigned and explicitly states that biomarkers were *not* used to make this judgment. Even though biomarker samples have been collected or biomarker data exist, they are irrelevant to this specific diagnosis as they were not used to support the diagnosis at that time.

**Scenario 4: Incorporating Biomarker Data in a Future Assessment**

1. **Situation**: Months later, biomarker data become available, but instead of holding a new consensus conference, the site carries this information forward to the next scheduled follow-up visit or future consensus conference.
2. **Future Use**: At the next year’s UDS follow-up visit or subsequent consensus conference, the newly available biomarker data are incorporated to inform the clinical and etiologic diagnosis at that time. ***ADRCs should not update the UDS data they have already submitted using the biomarker data that was available (or no biomarker data) at that time.***
3. **Documentation**: At the follow up visit, a new D1a form is completed, capturing any updated clinical diagnosis, and a new D1b form is used to document the etiologic diagnosis, now incorporating the biomarker information, if relevant. The original forms from the previous UDS visit and prior diagnosis remain unchanged, as they accurately reflect the clinical judgment made with the information available at that earlier time.

**Summary**

The D1a and D1b forms ensure clarity about what data were used in making an etiologic diagnosis at the time of the consensus conference. The aim is to provide a comprehensive yet flexible framework that accommodates varying timelines for biomarker data availability while maintaining data integrity. Sites can choose how to integrate biomarker information into their diagnostic process, and future clinical judgments should document any newly used biomarker data. This approach prevents the need for continuous updates to past diagnoses and ensures that all diagnostic decisions are based on the information available at the relevant time.