**Appendix No. 2 to Request for Bids No. 02/WPD104/2020**

#### ..................................., on .............. .............

 *(place) (date)*

**CONTRACTOR**

……………………………………….

*(name/registered office/address/tax ID (NIP) of the Contractor)*

**AWARDING ENTITY:**

WPD Pharmaceuticals sp. z o. o.

ul. Żwirki i Wigury 101,

02-089 Warszawa,

#### **DECLARATION OF COMPLIENCE WITH THE REQUIREMENTS INDICATED IN SECTION VI OF THE REQUEST FOR BIDS**

For the purpose of the contract award procedure coveringContract Research Organization (CRO) service, for the purpose of clinical trials development, conducted by WPD Pharmaceuticals, as a part of the project No. POIR.01.02.00-00-0084/18, entitled: “*New approach to glioblastoma treatment addressing the critical unmet medical need”* (Request for Bids No. 02/WPD104/2020), on behalf of the Contractor I hereby declare that

Company …………………………………………………………… *(Company name)*

Registered in …………………………………………………………*(Registered Address)*

meets the following conditions:

1. I declare that we have adequate knowledge and experience within the contract object and people declare that all data contained in the Bid capable of performing the order.
2. I declare that we are in financial and economic situation that will allow the contract to be performed with due diligence.
3. I declare that:
4. we have experience in the provision of CRO services in the field of organization and conducting clinical trials (including basket trials and adaptive trial design) at the requests of Sponsors**,** according to GCP, including documented experience in conducting at least four (4) clinical trials in oncology (in advanced solid tumors), **and** at least one (1) clinical trial in glioblastoma (GBM) in adult population, **and** at least one (1) clinical trial in oncology, in pediatric patients population;
5. we have completed successfully at least four (4) GCP inspections carried out by the FDA or EMA or other regulatory authority in the last five (5) years;
6. we have and engage to perform the contract persons with appropriate qualification and experience, including at least one (1) person with a specialized education (in medical sciences, pharmacy, biotechnology, veterinary medicine, chemistry or biological sciences or related fields) on the position of Clinical Research Associate (CRA), with at least six (6) years of experience in clinical trials monitoring including monitoring at least two (2) clinical trials in oncology and at least one (1) oncology clinical trial in pediatric population; due to cooperation with clinical sites located in Poland, dedicated CRA must be fluent in polish; **and** at least one (1) person with a higher medical education (specialized in oncology) with at least six (6) years of experience in medical monitoring and experienced in conducting at least one (1) phase I (first-in-human) study; **and** at least one (1) person with specialized education (in medical sciences, pharmacy, biotechnology, veterinary medicine, chemistry or biological sciences, or law or other related fields) with adequate knowledge in regulatory requirements and at least two (2) years of experience in regulatory procedures, including Sci Adv, ODD and PIP; **and** at least one (1) person with specialized education (in medical sciences, pharmacy, biotechnology, veterinary medicine, chemistry or biological sciences, or math or computer science or other related technical fields) with adequate knowledge and at least two (2) years of experience in data management; **and** at least one (1) person with specialized education (in medical sciences, pharmacy, biotechnology, veterinary medicine, chemistry or biological sciences, or related fields) with adequate knowledge and at least six (6) years of experience in clinical trials and team of monitors management.
7. we have adequate experience in operating electronic systems dedicated for clinical trials management and conducing, as well as data collection (e.g. documented cooperation with vendors/suppliers of eCRF, eTMF, eISF systems), and have a quality system in the form of at least standard operating procedures (SOPs) covering all necessary processes of organization and conducting clinical trials in compliance with GCP, such as: feasibility process, contracting, regulatory, study risk assessment, risk management and data protection.
8. we have experience in cooperation with clinical sites conducting trials in oncology.

**Curriculum vitae of the persons participating in the contract object preparation is attached to the Bid.**

1. I declare that all data contained in the Bid are consistent with the actual and legal status.

Place ………………, on ……… ……..................................................

*(signature of the person(s) authorized to represent the Contractor)*