|  |  |  |
| --- | --- | --- |
|  | TÜRK AKREDİTASYON KURUMU | F  701-108 |

|  |
| --- |
| **Biyobankalar için Akreditasyon Başvuru Formu** |
| *Accreditation Application Form for Biobanks* |
| **(TS EN ISO 20387)** |

**İlk akreditasyon** / *the initial accreditation* ☐

**Akreditasyon kapsamı genişletilmesi** / *the extension of accreditation scope*  ☐

**Akreditasyon kapsamı değişikliği** / *the change of accreditation scope* ☐

**Akreditasyon yenileme** / *the re-accreditation* ☐

**İnsan numuneleri Biyobankası/** *Human sample biobank***:**  ☐

**Diğer biyobanka** / *Other*: ☐

**Lütfen belirtiniz (hayvan, bitki, mikroorganizma veya hayvan ya da bitki olmayan çok hücreli organizmalardan veya bir parçasından elde edilmiş herhangi bir numune /** *Please specify**any sample obtained from, or part of, an animal, plant, microorganism, or multicellular organism, whether animal or plant:*

*…………………………………………………………………………………………………………………………..*

*…………………………………………………………………………………………………………………………………………………………………………….*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  | | --- | --- | --- | --- | | **Biyobankanın Adı / Tanımı** / *Name-Identity of biobank*  …………………………………………………………………………………………………………………..………………………………………. | | | | | **Adres** /*Address:* ……………………………………………………………………………………………………………………………………………..………….…………………………………………………………………………………………….……………………………………………………………….. | | | | | **Şehir**/*City*:………………………………..…… | **Posta Kodu** /Postal *Code*:………………… | | **Ülke** /*Country*:……………………..…..……… | | **Telefon ( Alan Kodu dahil )** */Telephone (incl.area code):*………………………….…… | | | **Faks /***Fax:*………..…..………………………… | | **E-posta** */E-mail:*…………………………………………………………..…… | | **İnternet Sitesi /***Website:* …………………..………..…… | | | **Vergi Dairesi** */Tax office:*………………………………………..…………… | | **Vergi No /***Tax no:* …………………………………………… | | |
| |  |  |  | | --- | --- | --- | | **Biyobanka Yöneticisi Adı Soyadı** / *Name and Surname of Head (Director/manager) of the biobank*  …………………………………………………………………………………………………………………………………………………………… | | | | **Telefon** */Telephone*:……………..…….…. | **Cep Tel** / *Mobile Tel*: ……………………… | **E-posta** */e-mail*:……………….…….…… | | **İrtibat Kurulacak Kişi Adı ve Soyadı /** *Name and Surname of Contact Person:* …………………………….…………………………..…… | | | | **Telefon** */Telephone*:……………..…….…. | **Cep Tel** / *Mobile Tel*: ……………………… | **E-posta** */e-mail*:……………….…….…… | | **Biyobankanın Yasal Statüsü** / *Legal status of the biobank*…………………………….…………………………..…… | | | |
| |  | | --- | | **Biyobankanın Yasal Sahibi** / *Owner of biobank:* ………………………………………….…………… | | **Biyobankanın Yasal Sahibinin Adresi** / *Address of the owner of biobank:*  ……………………………………………………………………………………………………………………………………………………………  **Biyobankanın Yasal Olarak Yetkilendirilmiş Temsilcileri** */ Legal representatives of the owners.*  …………………………………………………………………………………………………………………………………………………………… | |
| |  |  |  | | --- | --- | --- | | **Biyobankanın Personel Sayısı** **/** *Number of biobank employee:* …………………………………… | | | | **Biyobanka sözleşmeli harici personel çalıştırıyor mu?** / *Does the biobank employ contracted external staff?* | **Evet /***Yes*  **☐** | **Hayır /***No*  **☐** | | **Harici Personel Sayısı** **/** *Number of external staff:* ……………………………………………………………………………… | | | | **Harici personelin Biyobanka alanındaki sorumluluk ve görevleri** /*Responsibilities and tasks of the external personel in biobanking field*:……………………………………………………………………… | | | | **Kalite Sistemi Ne Kadar Süredir İşletiliyor** /*How long is quality system being operated?*  **0-3 Ay /***Months* **☐ 3-6 Ay /***Months* **☐ 6 Aydan Fazla /***More than 6 months ☐* | | | | **İç Tetkik Yapıldı mı ?** /*Was internal audit conducted?* | **Evet /***Yes*  **☐** | **Hayır /***No*  **☐** | | **Yönetimin Gözden Geçirmesi Yapıldı mı ?** / *Was management review conducted?* | **Evet /***Yes*  **☐** | **Hayır /***No*  **☐** | |
| |  |  |  | | --- | --- | --- | | **Biyobanka Faaliyetlerinin Yürütüldüğü Diğer Lokasyonlar /** *Other locations in which biobanking activities carried out*  **Şube/** *Site* **☐ Mobil Tesis***/ Mobile Facility* **☐ Geçici Tesis/** *Temporary Facility* **☐ Sanal Saha /***Virtual Site* **☐**  **Diğer Lokasyonlar(Temsilcilik, İrtibat Ofisi)/** *Other Locations (Representation Office****,*** *Contact office)****……………………….***  **(Diğer Lokasyonlara ait bilgileri lütfen EK 1 kısmında belirtiniz.)/** (*Please give the information about other locations in Annex 1.)* | | | | **Başvuru yapılan kapsamla ilgili faaliyetlerde taşeron kullanılıyor mu?**/*Are there any subcontracted services associated with your scope of application?* | **Evet /***Yes*  **☐** | **Hayır /***No*  **☐** | | **Başvuru yapılan kapsamla ilgili ölçümlerde kullanılan cihaz/ekipmanlara dahili kalibrasyon yapılıyor mu?**/*Are there any in-house calibration(s) of equipment used for any measurement activities associated with your scope of application?* | **Evet /***Yes*  **☐** | **Hayır /***No*  **☐** | |
| **Akreditasyonu istenen biyobanka kapsamlarını 3. Sayfada belirtiniz.**/ *please give the information about the biobanking scopes for which accreditation is requested at page 3.*  **NOT: Biyobankanın şubeleri mevcut ise, 3. sayfa çoğaltılarak her bir şube başvuru kapsamı ayrı ayrı verilmelidir.** / *If biobank has sites, the applications scopes must be given separetly for every site.* |

|  |
| --- |
| **Başvuran Biyobanka olarak TÜRKAK Akreditasyon Prosedürleri ile TÜRKAK kurallarını okuduğumuzu, anladığımızı ve aynı zamanda TÜRKAK Hizmet Ücretleri Rehberine (R10.02) uygun olarak tarafımıza fatura edilecek bedelleri ödeyeceğimizi taahhüt ederiz.** *As the applicant biobank we hereby declare that the TURKAK Accreditation Procedures and TURKAK Rules are understood by us and all costs that will be invoiced consistent with TURKAK Service Fees Guide (R10.02) will be paid by our biobank.*  (**Resmi Kaşe**/*Official Stamp*)  **Yer** / *Venue*: ……………………………………………………  **Tarih** / D*ate*: …………….…………………………….………  **Yetkili Adı Soyadı ve İmzası**: …………………….………  *Autorized Person’s Name-Surname-Signature* |
| **ÖNEMLİ HATIRLATMALAR /** *IMPORTANT REMINDINGS*  **Başvuru formunun ekine, “F701-071 Akreditasyon Hizmetleri, Uygunluk Değerlendirme Kuruluşu Yetkili Bildirim Formu” ile “F701-039 Akreditasyon Sözleşmesi” (2 Nüsha)**  **doldurulup yetkili kişi tarafından imzalanarak eklenmesi gerekmektedir. */****F701-071 “Conformity Assessment Body Representing Person Declaration for Accreditation Services Form” and F701-039 “Accreditation Contract” (2 copies) shall be filled, signed by authorized person and attached to this application form.*  **Başvuru Formunun ve eklerinin birlikte iletilmesinin ardından başvurunuz TÜRKAK Bilgi Sistemine kaydedilecektir. Bu işlemi takiben Kuruluşunuzun Yetkilisi tarafından denetim ile ilgili dokümanlarınız TÜRKAK Bilgi sistemine yüklenmelidir*./*** *After receiving the**application form and annexes, your application will be uploaded to TURKAK Information System. After this stage, applicant testing laboratory should upload requested documents to TURKAK Information System.* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Akreditasyonunu talep edilebilen süreçler aşağıda sıralanmıştır. Altı çizili süreçler zorunlu (asgari şart), diğerleri seçimlidir. /** *The processes for which accreditation can be requested are listed. Underlined processes are mandatory, others are optional* | | | |  |  |
| **Numune Alma/** *Collection:* **Taşıma /***Transport: :* **Depolama** */ Storage:*  **Hazırlama – Koruma /** *Preparation – Preservation:* **Paylaşım /** *Distribution:*  **Edinim /** *Acquisiton***:**  **Deney - Analiz /** *Testing - Analysis:* | | | |  |  |
| **Numune Alma Metodu (seçimli) /** *Collection Methods (optional)* (Venöz kan toplama, İdrar Toplama vb. / Venous Blood Collection , Urine Collection etc.) | | | | | |
|  |  |  |  | | |
|  |  |  |  | | |
|  |  |  |  | | |

**Akreditasyonu talep edilen Biyobanka Faaliyetleri** */Biobanking Activities subjected to accreditation*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Biyolojik Numuneler**  **/Ürünler****/**  *Biological samples/Products* | **Alt Kategori/***Subcategory* | **Faaliyetler** */ Activities* | **Depolama Koşulları** */Storage Conditions* | **Metodlar/***Methods* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Eğer yeterli sayıda boşluk yoksa lütfen ek için yeni sayfa kullanınız.** /*If there is insufficient space, please use a new page for this annex.*

**EK 1/** *Annex 1***Biyobankanın Şubesi/** *Site of biobank*

**Şube Ünvanı/** *Title of Site***:** ………………………………………

**Adres /***Address***:** ……………………………………………………………………………………………………………………………………………..………….…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….

**Şehir /***City***:** ………………………………..…… **Posta Kodu /***Code***:** ………………… **Ülke /**Country: …………………………….……

**Şube Yöneticisi Adı ve Soyadı/** *Name and Surname of Head of the Site Biobank:…………………………………………………..*

**İrtibat Kurulacak Kişi Adı ve Soyadı /** *Name and Surname of Contact Person***:** …………………………………………………………………

**Telefon /**Telephone: ……………..…… **Cep Tel /** *Mobile Tel: ………..……………* **E-posta /***e-mail:……………..…………………*

**Biyobankaya ait Diğer Lokasyonlar (Mobil Tesis Hariç)** */ Other locations for biobank ( except Mobile Facility)*

**Tesis Türü/** *Type of Facility : ……………..*

**Tesisin ilişkili olduğu Merkez/Şube /** *Related Head Office of Facility /Site of Facility*:……………………………………………………………………….

**Yürütülen Tüm Faaliyetler/** *All activities carried out:*

*……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….*

**Adres /***Address:* ……………………………………………………………………………………………………………………………………………..………….……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**Şehir /***City:*………………………………..…… **Posta Kodu /***Code: …………………* **Ülke /***Country: …………………………….……*

**Telefon ( Alan Kodu dahil ) /**Telephone (incl.area code): ……………….. **Faks /***Fax:*………..….………… **E-posta /***e-mail:……………..……*

***Mobil Tesis/*** *Mobile Facility*

***Tesis Türü/*** *Type of Facility : …………….*

***Tesisin ilişkili olduğu Merkez/Şube /*** *Related Head Office of Facility /Site of Facility :*

*…………………………………………………………………………………………..*

***Aracın Plakası/*** *Licence Plate: …………………* ***Aracın Şasi Numarası/*** *The Chassis Number of Vehicle:……………..*

***Aracın Marka ve Modeli/*** *Vehicle Brand and Model: ………………………*

***Yürütülen Tüm Faaliyetler/*** *All activities carried out:*

*……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….*

***Adres /****Address: ……………………………………………………………………………………………………………………………………………..………….…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….*